BUILDING RESEARCH PARTNERSHIPS

Facilitators' Manual and Resources

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About this resource

We designed this manual to assist in the facilitation of groups of people who would like to learn more about how to enable and empower the public to understand how to become effectively involved in health and social care research.

This manual has been written and designed to be used by facilitators who have completed Macmillan Cancer Support's 'Building Research Partnerships' facilitator training programme, although it will hopefully be useful to anyone with an interest in public involvement in research.

Audience

'Building Research Partnerships' is for anyone who has an interest in how the public can be involved in health and social care research. It has been written for a mixed audience of both lay people and professionals.

How to use this resource

This document includes a framework of learning areas and learning outcomes designed to support people to get involved in health and social research.

The learning areas have been divided into modules, with each module having associated activities and resources.

The modules in this facilitators' manual are self-contained and can be run individually; you can also combine these if you want to run longer sessions.This allows the option to choose specific modules and resources which can be used as required.

We have included suggested programmes which are appropriate for different levels and timings and allow a facilitator to tailor the learning plan appropriately. Timings are suggestions only.

This manual has been written so that **no formal scientific training** is required to use it or deliver training. It is designed for anyone who has an interest in public involvement in health and social research.

Local

When facilitating this course, it is important to adapt materials to include relevant local information such as contact details and information about local groups and organisations as well as details of any local research and documentation used by those organisations.

Share and share alike

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Table of Contents

About the course ‘Building Research Partnerships’

Summary: An exploration of health and social research and how the public can get involved and work with professionals in the research process.

Aim: To explore the various ways of how to actively and constructively involve the public in the research process.

Outcome: Participants will be able to apply their knowledge and experience in a practical way to help improve public involvement and participative decision making in research.

By the end of this course:

- Participants will be able to explain what research is, how it works and why it is important for lay people (patients, carers and the public) to work with professionals at every stage of a research project.
- Participants will be able to explain the process called the ‘research cycle’ and how the public can be involved in that process.
- Participants will understand the importance of partnership working for lay members, professionals and research staff

Please note: Because of the subject of this course, each session brings together a unique mixture of people with their own experiences, views and ideas. An essential part of this course involves participants interacting during the day so that they meet new people, share knowledge, find and create opportunities to apply the learning from the day.

As much as possible, this course has been designed to encourage participants to get to know relevant people, ‘network’ and build partnerships.

At the end of the day, people may wish to formally share details with other participants and this should be encouraged by the facilitator.

About the language used in this document

Please note the following definitions of the words used in this document:

- **Public involvement** - a term for involving patients and the public in health research. When we use this term, 'public' means patients, potential patients or members of the public including those with known genetic dispositions, carers and people who use health and social care services as well as people from organisations that represent people who use health and social care services. (Definition taken from the Health Research Authority 'Strategy for Public Involvement')

- **Lay person** - The word 'lay' comes from the Greek word 'laikos' which means "of the people". A layperson has come to mean someone who is a non-professional in a given field of knowledge. In this document it is used to describe someone who is **not** medically qualified or not a qualified professional involved in health or social care. The term could refer to patients, carers or any member of the public.

- **Facilitator** – someone who has completed training to become a facilitator for 'Building Research Partnerships' courses. The word **'**facilitator' comes from the Latin 'facilis' meaning 'easy'. In a literal sense, to facilitate is 'to make things easier'. Facilitators are not always subject experts, but attempt to draw on the existing knowledge of the participants, and to then 'facilitate' them to use their own skills as well as giving them access to training or further learning where gaps in knowledge are identified and agreed on. Facilitators focus on the foundations of adult education: establish existing knowledge, build on it and keep it relevant. The role is different from a trainer who would usually have expertise on a certain subject and may draw out and transmit knowledge on specific topics.

- **Associate facilitator -** someone who is being trained to facilitate 'Building Research Partnerships' courses

- **Senior facilitator** – someone who is permitted to train associate facilitators to run the 'Building Research Partnerships' course.

- **Resource** – this is anything which is in addition to this facilitator manual. The 'Information Resource' is the main resource, although there is also a wide selection of handouts, worksheets and other background reading materials in the 'Handouts and worksheets' resource.

- **Centre –** an organisation or group who are organising a course to be run.

Facilitator learning activities

This section contains notes on how to run activities.

This is an example agenda for this course. It usually runs from 9:30 – 4:30pm with a free lunch included and a break in the morning and afternoon.

Module number	Module title	Summary	Timings (minutes)
1	Introductions	Introductions and expectations	20
2	Group agreement	Establish participants' needs and create a confidential and trusting learning environment	15
3	What is research?	An exploration of the meanings of the word 'research'	20
4	Research Methods and terminology	How research is conducted and the terminology used	45
5	The research cycle and lay involvement	How and where the public can be involved in research	45
6	Research Funding	An exploration of research spending and funding sources	20
7	Communicating Research	An examination of how research is communicated	45
8	Current research and involvement of the public	Current examples of local research and how the public are involved	45
9	Group working	A discussion about the terms role, remit, responsibilities, representation, relationships and readiness.	45
10	Recruitment	How involving people can assist the process of recruiting participants to research studies	45
11	Pass it on	Sharing learning, action planning and closing.	30-40

EXAMPLE ACTIVITY

EXAMPLE SUBTITLE

This references the relevant chapter of the resource

Area of Learning: This is the defined area of learning or subject that this activity covers. For example 'Fire safety'

Learning aims: A learning aim is the purpose or reason for exploring this area of learning. For example, a learning aim might be 'To understand the importance of fire safety and help save lives'

Learning outcomes: An 'outcome' or result of this learning should be that the learner knows, or can do, certain specific things. For example, 'The learner is able to explain the importance of fire safety'. Because the outcomes can be quite broad, most areas of learning have the *key learning points* listed, which is an attempt to articulate the essential details and facts (See below).

Key learning point: This is the essential knowledge that must be communicated by the trainer and understood by the learner. It is often more specific than the outcomes and measures and is designed to be used to help assess learning. For example, some key learning points might be 'A knowledge of the location of all the fire escapes in the building' or 'The knowledge that lifts must not be used in a fire'. **In some cases, it may be important to add 'local' or specific information that applies to where the learner will be applying their learning**. For example 'The fire alarm is tested at 10:30am every Friday in this building and the learner should react appropriately'.

Application of learning outcomes

Some chapters will have the application of learning outcomes explained. This is where it might not be obvious how this learning can be practically applied. An example of applying a learning outcome would be 'knowing what to do when you hear a fire alarm, knowing where the nearest exit is, finding the nearest exit and exiting from it safely' as opposed to a more abstract understanding of the concept of 'fire safety'. Another specific application of learning could be 'knowing not to exit the building upon hearing an alarm at 10:30am on a Friday'.

Learning assessment

None of these activities has a formal assessment, but much of the learning can be assessed informally through the use of questioning, asking a learner to summarise or observation. Checking an understanding of the key learning points will help ensure the aims and outcomes have been met.

Learning activities

Area of Learning: for clarity, the area of learning is assigned to an activity

These are suggested activities, resources or handouts. These can be worked through with the learner to help explore the key learning points in (hopefully!) an interesting and engaging manner. Because all learning activities are suggestions, they provide an opportunity for any facilitators to develop or use their own resources. The learning activity can be very flexible, as long as the aims, outcomes and the key learning points have all been met. In these notes, there may be more than one activity for each area of learning. Facilitators may chose which to use or design their own.

Resources

These are the relevant handouts or resources that you could use for the activity.

WELCOME AND INTRODUCTION

Fifteen minutes

Reference: Module 1

Area of Learning: Welcome and introduction

Learning aims:

- To welcome people to the day and ensure that participants feel comfortable and relaxed
- To provide a general outline of course, why and how it is being run along with a brief background
- To give participants chance to introduce themselves

Learning outcomes:

- Participants will be able to explain the purpose of the day

Key learning point:

- The facilitator's role is to aid group discussion and shared learning
- Participants know about the fire safety arrangements
- Participants know the intended timings for the day including the finish time and lunch arrangements
- Participants are comfortable with the word 'lay'

Please see the next page for learning activities for this area of learning.

Learning activities

Area of Learning: Welcome and introduction

Lead a conversation about the day using this script below:

About the course:

This course is an introduction to getting involved in research and the different ways in which people can work together in partnerships to improve the quality of research preparation, planning, delivery and application.

Why we are doing it:

Research is for everyone, and everyone can help shape the future of research.

Macmillan has been working to help patients and the public get involved in research many years. We know that by putting the needs of patients and the public and at the centre of all research, we can ensure many more lives are improved by it.

By supporting people to get involved in research and by helping researchers and funders of research work in partnership with the people they are trying to help, we can:

- Help prioritise what kind of research is funded
- Help research to be better planned
- Improve the experience of research participants
- Ensure the results of research are shared and translated into improved care

This can only be achieved by patients and the public working in partnership with Governments, academics, and industry. The role of charities is central to ensuring that everyone has a chance to help shape the future of research.

Fire safety and domestics (see 'ready to start?' section)

Style and delivery

Macmillan promotes any kind of learning environment which encourages shared learning, group discussion and experiential (active) learning.

The idea that we all have something to give and something to learn is central to any of our learning opportunities and all our facilitators are encouraged to create a space in which people feel they can share openly.

Where possible, the facilitator's role is to encourage participants to share their existing experience and knowledge both in small groups and to the room.

For more detailed information, see the section on 'Delivery style'

Language

Explain the term 'lay' and why it is used. Reinforce that all acronyms should be avoided as these can alienate people.

Background

Public and Patient Involvement in research was founded many years ago in the areas of Maternity and Mental Health Services and became more widespread when HIV patients began focusing on getting involved in the decision making about their own health. This course was originally designed at the start of this millennium to meet the needs of cancer patients and carers. It promoted best practice through

networking, sharing good practice and building partnerships. It was such a successful model that it was adapted so that it is relevant to all types of health and social research, not just cancer. We can all learn from each other and achieve more by working together. To reflect this, the course's audience comprises a mix of professionals and members of the public.

Caution

This is not the explanation of everything to do with research and patient/lay involvement – It is opportunity to become familiar with some of the terms, its language – imagine it as a day trip before going to live in another country – new language, dialect (jargon) as well as climate and culture. This is the start of a journey. There is NO test at the end to check on knowledge gained but hopefully an appreciation and some inspiration!

Action

We also want to help you leave having committed to a few actions or next steps.

Resources

Flipchart and pens

GROUP AGREEMENT

Fifteen minutes

If you have more than 12 people, allow an extra 1 minute for every person over this number

Reference: Module 2

Area of Learning: Establish participants' needs and create a confidential and trusting learning environment

Learning aims:

- To identify participants' needs, course expectations and concerns.
- Establish a group agreement about the way the group will conduct itself and work together for the day
- Agree specific issues or areas that the group would like to cover during day

Learning outcomes:

- Participants will be able to explain what learning outcomes they have
- Participants will be able to explain and recognise the importance of having a diverse group of people working towards the same objectives
- Participants will be able to explain the importance of a group agreement

Key learning point:

- This is a confidential environment, anything said here is in confidence
- The day can be adapted to meet the needs of the group (within the outcomes of the course)
- Acronyms should not be used without an explanation of what they stands for.

Please see the next page for learning activities for this area of learning.

Learning activities
Area of Learning: Establish participants' needs and create a confidential and trusting learning environment
Ask in small groups or pairs: • What people want to gain from the day. • What they will be able to give or offer the group (e.g. expertise/experience) • Do they have any concerns (e.g. anything they're worried about – such as acronyms or role play). Depending on numbers you may wish to gather feedback in pairs, as a group exercise or as a 'round the room'. State the you would like to make a group agreement. Ask people what kind of things they'd like in the group agreement for how the group will work that day. Log these on the flip chart. (Hints: equal voice, all equal, no right/wrong answers, confidentiality, respect, different opinions are welcome, questions) Agree vocabulary – explain the term 'lay' and why it will be used throughout the day and that no acronyms will be used at all. A final question that is helpful is 'is there anything specific that people want to cover that has not been mentioned'. This provides opportunity to identify any potential specific enquiries and problem solving e.g. tissue collection; parents and children – whose research; Public engagement; Involvement at the initial stages of research, etc. State that the group will revisit this at the end of the day to see if all areas have been covered and needs met. At this stage, you may want to start thinking about whether you plan to divide the group for certain sessions if needs are very diverse. Remember you want interaction between professionals and lay people so use this activity to identify the mix.
Resources
Flip chart, pens

WHAT IS RESEARCH?

Twenty minutes

Reference: Module 3

Area of Learning: An exploration of the meanings of the word 'research'

Learning aims:

- To help define what is meant by the word 'research'
- Focus participants on the whole research process, rather than just the outcomes

Learning outcomes:

- Be able to explain the terms ''research'' and ''development'' and how research can affect health and social care.

Key learning point:

- Research can mean many things
- Research can be understood as trying to answer a question
- Research is a way of increasing our understanding using a systematic method in a way which is regulated and reviewed by scientific peers and the public

Application of learning outcomes

- Be able to understand the wider context of research when in meetings or communicating with others.

Please see the next page for learning activities for this area of learning.

Learning activities

Area of Learning: An exploration of the meanings of the word 'research'

Ask each delegate to give you a single word or phrase which reflects their idea/concept of what the word ''Research'' means. Invite participants to consider it in the widest sense.

Obtain an answer from every delegate (e.g. research is: asking a question). As each gives their answer write it down, if multiple answers to a word or phrase just put a 'tick' next to that item.

Be prepared to have use a stock of examples to explore the subject

Mention that most of the public actually do research daily without realising that is what they are doing. For example, ask if anyone has been on holiday lately or bought a gadget. Did they look at a number of brochures, did they look at what was on offer at different websites, did it meet their needs etc. Explain to them that what they did was exactly the same as professional researchers. They had a question, examined the evidence and looked for the answer.

Mention that sometimes research can begin with someone just observing a pattern and forming an idea from that. During feedback challenge the breadth of explanations and explain that it can mean anything from an audit through to a randomised control trials or something very basic.

When describing who is involved research ask participants to list the roles they know and describe them. Some examples include:

Professional involved in research	**Public**
Researcher, Scientist , Data manager, Doctor, Research Analyst, Research Nurse, Principal Investigator, Research Manager	We are all potential patients, some of us will be genetically pre-disposed to some conditions and may or may not (or may not want to) know. Some of us are already patients, are former or past patients, carers or care givers. In a health economics sense, we are consumers, service users or even customers. Some of us are research partners.

- 'Basic Research is when we don't know what we are doing' Einstein.

Now ask people **why** we do research (typical answers are 'improves lives', 'happier', 'better quality of life').

Now ask people why you should **involve the public** in research.

Tell the 'Why we involve the public' story from the 'Stories and facts about public involvement in research' [Resource 17] or use any from your own experience.

If you have a large number of professionals – consider giving them a separate activity. Ask them:

- How have you involved the public in research in the past?
- Do you know of anyone else who has involved the public in research or is currently doing so?
- What worked well, what didn't?

Resources

- Flip chart
- 'What is research? Stories and facts about public involvement in research' [Resource 17]

RESEARCH METHODOLOGY AND TERMINOLOGY

Forty-five minutes

Reference: Module 4

Area of Learning: How research is conducted and the terminology used

Learning aims: To introduce some of the language and methods of research and how our perceptions are affected by media coverage

Learning outcomes:

- Be able to explain the different methods of research used and the language used to describe it
- Explain what critical appraisal is

Key learning point:

- The public have an important role to play in helping better research happen.
- It is always important to ask questions about research and critically appraise it
- Always consider who is funding research and why
- Once the research question has been set, the same thing should be measured all the way through and the way it's measured comparable to other studies.

Application of learning outcomes

Understand language used to describe research and be able to examine media reporting of studies in a more careful way

Please see the next page for learning activities for this area of learning.

Learning activities

Area of Learning: How research is conducted and the terminology used

Activity 1

Explain that there are a variety of research methods. Explain that the terminology is there to ensure everyone, both those doing the study as well as anyone enquiring about it, understands the process under which that particular research study is being undertaken (**3 minutes**).

By now you should have an idea about who your lay and professional delegates are. Split them into mixed groups with, as close as possible, equal mixes in each. Distribute the 'Types of research' resource and the 'Blank definitions of research' resource and ask each group to choose a spokesperson and then to match the title with the description (you may want to produce cards that people can place on the terms). Leave the groups to work for about 5 minutes and give them a minute's warning before ending the session. Allow (**10-15 minutes**).

Highlight this to the entire group that there are arrows on the sheet (one pointing to the future, the other to the past) and explain that this is a hint as to the type of research each one relates to.

Asking the groups to give their answers. Then use an example of each to ensure they understand the process named (use 'Definitions of research' resource for real life examples) (**10 minutes**)

More advanced - Translational research

If the group is more advanced, then explain phase I, II and III stages of research. Use 'Translational Research' [Resource 18]. Answers: Phase one =Z, Phase two= X, Phase three =Y.

If time (and interest) carefully lead a discussion asking people what they know about animal testing. If appropriate, ask them how they think ethics apply to animal testing and how this can work in practice.

Resources

Activity 1 – 'Types of research' [Resource 1] , 'Blank definitions of research' [Resource 2], 'Definitions of research' [Resource 3], 'Translational Research' [Resource 18].

See next page for Activity 2.

Learning activities

Area of Learning: How research is conducted and the terminology used

Activity 2

This activity can be done in a number of ways. Here is one suggestion:

- Give people 'Global Daily News' [Resource 9] and ask them to comment on the article about anything they can think of
- Give people 'LOMA trial fact sheet Phase III' [Resource 8] and ask them if they would take LOMA. Do they have any questions about the research?
- Explain terms from the 'Common Terms' [Resource 5] as they come up or make it more interactive by asking people which terms they think are relevant or getting them to match the definitions.

OR

- Ask people to read 'LOMA Phase II clinical trial advert' [Resource 6] or consider asking someone to read out the first page.
- Surprise the group by asking them what they think is **good** about it. Remind them the role of the public is to help make research better.
- Give them 'Questions to ask about research' [Resource 5] and ask them to discuss in groups if they have any questions or comments about the advert and patient information sheet. Consider asking different groups to consider different issues.

Some important points to highlight are:

- The trial has illegally recruited before ethical approval
- Patient experience on the trial and potential recruitment issues.

This activity can be a useful 'leveler' before asking people to look at real examples of local research.

Resources

Activity 2 - 'LOMA trial fact sheet Phase III' [Resource 8], 'Global Daily News' [Resource 9], 'Common Terms' [Resource 10] 'Questions to ask about research' [Resource 5], 'LOMA Phase II clinical trial advert' [Resource 6].

THE RESEARCH CYCLE AND LAY INVOLVEMENT

Forty-five minutes

Reference: Module 5t

Area of Learning: How and where the public can be involved in research

Learning aims: To use the research cycle as a basic model for understanding the different stages of the research process and to explore the added value of public involvement

Learning outcomes:
Participants will be able to explain:

- The various stages of the research cycle.
- The importance of involving the public at every stage and the ways people can get involved.
- The difference between 'patient and carer' involvement, 'lay' involvement and that the word 'public' encompasses them all, but sometimes needs articulating.

Key learning point:

- Anyone can get involved at any stage
- There is often a mandatory requirement to involve the public in the research process, and it is certainly best-practice
- By supporting people to get involved in research and by helping researchers and funders of research work in partnership with the people they are trying to help, we can:
    - Help prioritise what kind of research is funded
    - Help research to be better planned
    - Improve the experience of research participants
    - Ensure the results of research are shared and translated into improved care

Learning activity: The research cycle

Area of Learning: How and where the public can be involved in research

Activity 1 (20 minutes) Explain:

- This activity is designed to give a basic understanding of the process known as the ''Research Cycle''. There is no one model but the one we use is designed to be a helpful overview of the research process.
- Many of the activities in the cycle can overlap and occur more than once.
- Consider asking the group why it is called a 'cycle' (because research never ends, and often it ends with more questions).

There are two ways this activity can be done and it depends on the size of the group or the room space.

The first way is:

- Get small groups to take the stages of the research cycle and place them in a clock-wise order
- Bring the group back together. Ask one group to identify their first card in the cycle and ask if the other groups agree/disagree. Ask if anyone has been involved in that stage of the cycle or if they have involved the public in that stage.
- Move onto the second card and ask another group what their one is (and so on).

The second way is:

- Give some people cards with a stage of the research cycle and to sit or stand in a circle and hold up a stage of the research cycle. *If asking people to stand, make sure it's not for too long and that those unable to stand are not excluded.*
- Then ask people to move around until they are standing in order. Allow discussions to take place, reminding people of how many activities overlap or occur more than once.
- Only interject if you feel they people are losing interest, getting frustrated or if time is short
- Once the cycle is complete, ask people to stand near a stage of the cycle that they have been involved in, or if they have involved the public in that stage. If no one is able to do this, have some examples ready for each stage.
- Bring the group back together. *Consider asking people to bring chairs and sit as they are standing if everyone is standing.*

When you have completed either of these activities, ask people again where the public can be involved. Use 'Public involvement in research cycle' [Resource 21. For further development, see the next activity 'What does involvement look like?'

Resources

'Research Cycle' cards [Resource 16], 'Public involvement in research cycle' [Resource 21]

Learning activity: What does involvement look like?

Area of Learning: How and where the public can be involved in research

Activity 2 (20 minutes):

If time, start this activity by asking people to stand next to the printed signs from 'So what did you do?' [Resource 15] (or just point to areas of the room) . Ask them to think of a time they experienced something good, or something that could be improved with a health or social care service. The involvement can range from going to 'Llareggub' (a fictional Welsh village created by Dylan Thomas – try reversing the name!), through to filling in a survey, joining a focus group, joining a committee to contacting (or becoming!) and elected representative.

Introduce the handout 'Range of public and patient involvement' [Resource 14] and use it to emphasise the way in which some involvement is not true involvement and how the areas in the ladder show where it is really meaningful.

Use the 'facts about public involvement in research' resource to illustrate the importance of public involvement.

Ask the group what they think the difference is between 'public involvement', 'patient involvement' and 'lay involvement'. Ask them to think of examples of where the different kinds of involvement might be most appropriate. For example, patients might have a very specific idea of what needs researching, carers might identify other perspectives, where as any 'lay person' might be able to read something to check it makes sense or be involved in Ethics Committees.

Use the 'Patient and public involvement' [Resource 13] handout to illustrate different support needs people might have for various roles.

If time or appropriate, get the group to help you draw a diagram of the research cycle. Get them to tell you every organisation they know which is involved at each stage and supplement with your own knowledge.

Lead a discussion about publishing results, open data and linked data and discuss how this could affect the future of research. Use What did open data ever do for us? [Resource 19]

Resources

- 'Range of public and patient involvement' [Resource 14]
- What did open data ever do for us? [Resource 19]
- 'Patient and public involvement' [Resource 13]
- 'So what did you do?' [Resource 15]
- 'Stories and facts about public involvement in research' [Resource 17]

RESEARCH FUNDING

Twenty minutes

Reference: Module 6

Area of Learning: An exploration of research spending and funding sources

Learning aims: To help explain the importance of funding in the research cycle by examining research spending and funding sources

Learning outcomes:

- Be able to explain how research is funded and some of the factors regarding why some is and some isn't

Key learning point:

- It is mandatory for all research applications to the National Institute for Health Research to provide evidence of public involvement.
- Most research conducted in the UK is paid for by share-holder funded organisations from areas such as the pharmaceutical industry.
- While many organisations focus on health and social research, all kinds of research impact on everyone's lives in **often unpredictable ways**. For example, the Diamond particle accelerator in Oxfordshire is helping us understand how we can reprogramme T-cell receptors to attack cancer cells.

Please see the next page for learning activities for this area of learning.

Learning activities

Area of Learning: An exploration of research spending and funding sources

Lead a discussion about research funding.

Ask what kinds of funding delegates know about (government, charity and industry). Ask people how much they think is spent in total on research annually in the UK by the Government? Ask people to think outside of just drug trial funding, what about medical devices? Tissue research? Screening? Research into new techniques and practices.

Read out any/all research funding facts from 'Research funding facts' [Resource 23] (check they are up to date!):

If time, or interest, lead a discussion or debate using the hand out 'Creating an incentive for discovery' [Resource 11].

Ask 'who should pay for research'. Asking for a show of hands for people who think 'government' and people who think 'private' can be interesting. Asking people to debate one side or another (especially if it's the opposite of how they raised their hand) can be interesting. The conclusion is often that everyone should pay, but co-ordinated by Governments with the public and patients involved throughout. Supplement the discussion with the handout 'The public and the private interests - research and pharmaceutical companies' [Resource 20] or give people to take away.

If time, or interest, talk about the 'Haldane Principle' [Resource 22] and ask the questions on the hand out.

Resources

- 'Creating an incentive for discovery' [Resource 11]
- 'The public and the private interests - research and pharmaceutical companies' [Resource 20]
- 'Haldane Principle' [Resource 22]
- 'Research funding facts' [Resource 23]
- Any appropriate local resources on research funding.

COMMUNICATING RESEARCH

Forty-five minutes

Reference: Module 7

Area of Learning: An examination of how research is communicated

Learning aims: to examine the importance of effective communication in research

Learning outcomes:

- Be able to explain why good communication is essential to all audiences
- Be able to explain the principles of good patient information in all formats
- Be able to explain why different language may be necessary for different audiences and give examples.
- Be able to explain the purpose of and identify plain English organisations, such as the Plain English Campaign and their Crystal Mark

Key learning point:

- Informed consent relies on clear communication
- Clear communication helps spread the message and learning of research by making it easier to share
- Good communication helps recruit more people onto trials and could save the NHS millions every year in wasted applications and failed trials.
- A small budget for involving the public to go towards things such as transport costs can therefore indirectly save the taxpayer millions.
- Some researchers and professionals might need support to work with the pubic and listen effectively
- Involving the public in dissemination can be important

Please see the next page for learning activities for this area of learning.

Learning activities

Area of Learning: An examination of how research is communicated

Activity 1 (25 minutes): Distribute an example of ‘’poor’’ participant information (being careful to redact identifying details if necessary!) or use ‘LOMA Phase II clinical trial advert’ [Resource 6] or ‘A real example of a trial’ [Resource 7] if not used already. Make sure the whole group has the same information.

Give them 10 min to complete the review and then go round the room asking each pair/group to state **what was good about the information**. Once this is completed, ask the group what could be improved about these. Reiterate that the role of the public can be to help improve research and make it better and that it is often helpful to start about what is good when giving feedback.

Discuss: Language (plain English, only English?), medi-speak, acronyms, font size, use of pictures and size of documents, accessibility, format (digital/online/e-book/audio/mobile etc)

Tell the group that a majority of applications for funding are rejected because lay summaries are poorly written. In 2012, 68% of applications for funding were rejected because the lay summaries were poorly written. (Citation for statistic needed)

Using the comments highlight how having a lay member/reviewer could have influenced the document and why it may have improved it. Also ensure you record positive comments that can be used as best practice examples in the future.

Activity 2 (15 min)**: Scenario**: During the design stage of a study the researchers described who they thought should receive the results of the study and how that information should distributed. They did not describe any way in which the people who may benefit from seeing that information (current/future patients) would find out about the research. The group has been asked to rectify this and put in place a programme that will ensure all the information gets to the right places.

Split the delegates into 3 groups and ask them to devise a plan of distribution. Ask them to list: who needs to see it, how they should access it, where it should be publicised and how to get maximum publicity. **HINTS:** conferences, disease specific charities, patient forums, GPs, newspaper medical pages etc.

Activity 3 (5 min): Encourage participants to create a ‘ten golden rules’ of patient information sheets (small groups creating 3 each might work best)

Summarise: Ask the group if they now see the benefits of ensuring a good communication strategy is established right at the start of a study and why? Can they see the advantage of a collaborative ‘we’ way of thinking, not an ‘us versus them’.

Resources

LOMA Phase II clinical trial advert [Resource 6], 'A real example of a trial' [Resource 7]

CURRENT RESEARCH AND INVOLVEMENT OF THE PUBLIC

Forty-five minutes

Reference: Module 8

Area of Learning: Current examples of local research and how the public are involved

Learning aims:

- To identify research that is currently being undertaken in the local area of the delegates attending.
- To show the reality of research by using information from those local initiatives and how local public involvement should and could influence that research.
- An opportunity to share best-practice for involving the public.

Learning outcomes:

Participants will be able to explain:

- What research is happening locally and who is involved.
- The importance of influencing relevant literature
- Local circumstances and how they can access relevant people and influence future research.

Key learning point:

- You do not have to make major changes to have an big impact, small changes are just as significant
- An important role the public play is helping better research happen

Please see the next page for learning activities for this area of learning.

Learning activities

Area of Learning: Current examples of local research and how the public are involved

***Please note**,* in preparation for this activity it can be very valuable to ask a local researcher to come and talk about their research. They may wish to talk about how they have involved the public, or, if they are planning research they may ask for support in the best ways to involve people moving forward. It can sometimes be most effective to ask the person from the local centre to arrange for this person to talk.

This activity can begin with a local researcher talking for around 5 minutes about their research. Before they speak it is important to remind participants that the role of the public can be most helpful when offering constructive criticism on how the research could be improved. With this in mind, they should frame any comments from the perspective of 'how can we help make this research better'.

It can be helpful with some groups to use the 'LOMA Phase II clinical trial advert' [Resource 6] and 'A real example of a trial' [Resource 7] and ask them ask them what was good and what could be improved. By seeing a fictionally poor example of an information sheet and asking them to improve it, this can help the group focus on how to improve, rather than criticize unconstructively. Here are some things to consider asking the researcher to focus on:

- What are they trying to achieve with the research, or what do they want to learn?
- How was the need for the research discovered? Who chose the topic for the research?
- Who agreed it could go ahead?
- How have they involved the public in their research? How were these people recruited or selected? Did they train any members of the public to get involved?
- What worked well when involving the public, what was a challenge? How do they plan to involve people in their future research, would they do anything differently?
- Do they have anything they can hand out about the research, can the group help with anything in particular during their feedback?

Lead a discussion with the group and facilitate a question and answer session with a focus on public involvement. After the local researchers have finished, ask participants to share examples of research they may personally have been involved with.

Distribute the '"Ways of getting involved" diagram and consider distributing a blank one along with it. Working in groups get them to identify where they fit on the map and which organisations they know they can get involved with locally and nationally.

Resources

'LOMA Phase II clinical trial advert' [Resource 6], 'A real example of a trial' [Resource 7] "Ways of getting involved" [Resource 33] and 'Ways of getting involved blank version' [Resource 34], Material brought in by research delegates.

GROUP WORKING

Forty-five minutes

Reference: Module 9

Area of Learning: The principles of effective group working

Learning aims: To explore practical best practice which can make group working more effective

Learning outcomes:

- Be able to explain the importance of the interactions within a group and the responsibilities of being a team member in a meeting
- Be able to explain why 'Terms of Reference' are important for a group and how its structure operates

Key learning point:

- It is important to establish clear, concise rules and an understanding of the reason or purpose for the group or meeting. Never be embarrassed to ask or clarify this.
- By using Maslow's hierarchy of needs and asking few important questions, the '6 Rs' can be established. This can also help ensure people's basic needs are taken care of before a successful meeting can take place

Application of learning outcomes

Be able to be a constructive and active participant in a range of group-working situations.

Learning activities

Area of Learning: The principles of effective group working

Activity 1: Ask participants if any of them participate in what would be described as ''formal meetings''. Does the group have any comments on the various examples given and explore any issues. Ask them to discuss things that made it work or not work (5 min).

Explain Maslow's hierarchy of needs and consider drawing it up on a flipchart (3 min)

Divide the group into 3-4 separate groups and give them key questions from 'Group working (6Rs) and Answering important questions using Maslow's 'hierarchy of needs'' [Resource 12] to ask at meetings.

Ask them to place the questions on the hierarchy (they can stick them with a post-it or say it out loud). Then give people the handout and see if people agree with the order. On the reverse is the 6 R's handout. Ask them, in small groups at first, to discuss a section per group and summarise how this is relevant to public involvement in research (10 min).

Bring the whole group together and begin to discuss each section. Invite groups to compare each with their comments from the first part of the activity about Maslow (10 min).

If time, open up the discussion to explore different types of future involvement and how they see it working in reality.

Activity 2(15 mins)**:** Divide into groups to look at one each of the following four options and ask what questions they would have if there were chosen as a research partner working in a research team and were:

1. There as a group representative.
2. There because of their own experience as a patient or carer
3. There as they have been nominated by a funder and is there to represent that organisation.
4. There to provide a lay perspective

At the same time as this activity, consider separating professionals into a group of their own and ask them to think about the questions they would have in this scenario: 'You have been asked to speak at a Select Committee'. That is all they know.

Get feedback from the professionals first about the questions they would have. Often they are simple things like 'why am I there?', 'where is it?' or 'what should I wear?'. Explain the parallels about being in an unfamiliar situation. Ask the other groups to add any additional questions they might have for each category and encourage the group to come up with actions that will support people to be involved.

Resources

'Group working (6Rs) and Answering important questions using Maslow's 'hierarchy of needs'' [Resource 12],

RECRUITMENT

Forty-five minutes Reference: Module 10

Area of Learning: How involving people can assist the process of recruiting participants to research studies

Learning aims: To explore how patients, carers and the public can work together with researchers to help consider and advise on the issues of recruitment to clinical and other studies.

Learning outcomes:

- Be able to describe the ways in which involving the public can improve recruitment
- Be able to describe practical and relevant examples of public involvement in recruitment
- Be able to explain effective methods for engagement and involvement

Key learning point:

- Involving the public in the design or research and in reviewing information for participants is proven to improve recruitment

Application of learning outcomes

Be able to explain the advantages of involving the public in recruiting to research and suggest practical methods for doing so.

Learning activities

Area of Learning: How involving people can assist the process of recruiting participants to research studies

Agree a definition of the word 'recruitment'. Clarify that this is discussing recruiting participants to trials and other kinds of research, not recruiting people to reference groups etc.

Ask three questions:

- What do we mean by 'recruitment'? (What does it look like?)
- Why is the way we recruit important to potential participants?
- Why is it important to recruit people to studies?

Answers will include importance of sample size and better research, etc

Ask - Why is recruiting important? (10 min)

Small group discussions to focus on purpose of session

Ask - What can't the public be involved in? (5 min)

Q&A to ensure everyone is clear about ethics and governance

Mention the 'research buddy' programme, where people who have been on trials are put in touch with people who have been given information about trials. The idea is that they might be able to tell them what the experience was like, and may be more reassured to hear it coming from a patient, rather than professional.

Ask small groups to read and consider real examples from 'Recruitment Examples' [Resource 28]

Note: The following examples illustrate different things:

Dentures Study (Sue Pavitt) – SPECIFIC GROUP

Diabetes Studies (Mela) - PLACE

Mental Health (poster that was changed) – LANGUAGE (plain English, only English?)

Dementias (carers training) - APPROACH

Cancer (often after diagnosis) – TIMING

Ask groups to look at three different aspects of active involvement – *informing* research, helping to *form* and *influence*. List ways in which each of these might be achieved and what value to research. Use 'Insight to Foresight' [Resource 29]

Ask members of the group to discuss their own research and to work in pairs or groups to create a simple list of actions they could take to improve recruitment

Resources

'Recruitment Examples' [Resource 28], 'Insight to Foresight' [Resource 29]

PASS IT ON:
SHARING LEARNING AND ACTION PLANNING

30-40 minutes Reference: Module 11

Area of Learning: Action planning and sharing learning

Learning aims: To give an opportunity to make an action plan about next steps and to think about how to help others learn about commissioning.

Learning outcomes:

- Participants will leave being able to explain the importance of public involvement in influencing research
- Participants will be able to state where to go next and who to contact if they want to either get involved or involve the public in research
- Facilitators will be able to explain what was found useful in the day and feedback to other facilitators
- Participants can recognise barriers to explaining how the public can be involved and can support others to be involved by summarising solutions.

Key learning point:

- Co-operation between professionals and the public leads to more positive outcomes in research which helps both those undertaking the research and also those who will benefit from the results of that research.
- Getting involved in research can seem complicated, but explaining the basics and some starting points can be very simple.
- By taking the time to explain these ideas to other people, you are helping strengthen public involvement

Application of learning outcomes

- Knowledge of where and how the public can be involved in research.
- Be able to become active, constructive members of research projects studies
- Supporting others to understand how and where they can get involved

Please see the next page for learning activities for this area of learning.

Learning activities

Area of Learning: Action planning and sharing learning

Part one

- Ask participants to try and reflect on everything they have learned today or a resource they thought was really useful. You might ask them to close their eyes or think for a moment in silence.

- Ask them to pick one thing that they think is really important from the day.

- Ask them to get into pairs or threes and share what they thought was important – a key point, the headline or something they didn't know before.

- Tell participants to take it in turns to try explaining that one idea (A) and link it to an action someone could take or a way they could be involved (B). For example 'I hadn't heard of Ethics Committees (A) – you can get in touch and volunteer with your local research ethics committee (B)'. Give them a few minutes to prepare and gather relevant resources.
- Give them 2 minutes (no more) to try and explain their A and B points. Once they have both had a chance to try explaining their key point from the day, ask them to tell each other how they found the experience of sharing this knowledge or information. This can also be done as a whole group activity, or by asking people to volunteer to say how they found it.

Note: by only giving two minutes to explain, it creates a pressure on time. The learning point for this activity is that it **is** difficult to explain but that with practice and the right resources, it can make more sense (see key learning points)

Part two

- Ask the pair to work together to complete their own action plan. This could include something they will do, or something they will try to help someone else understand. For example 'I will explain to my group what an ethics committee is and how they can be involved.

- Ask if anyone would like to share their next action with the group. If appropriate (and agreed before hand) ask anyone from the local organisation to talk briefly about the day and what they hope the next actions will be.

Closing

Review the group agreement activity: were all the ''gains'' stated at the start satisfied, if not why not? Were all the ''gives'' appreciated and did the group see the benefit of working together on a common problem? Did the anticipated group agreement work; did everyone see how establishing that at the start allows all to contribute? Make the point that in effect it served as a short 'terms of reference' for the group.

Make sure you ask all the following questions in some form:

- Are delegates more confident now about getting involved?
- Do they feel they have the skills to do so? If not, do they know where they might develop them?
- Do delegates see that the process is not as complicated as they might have imagined?
- Does anyone think they will work with other people after today, or contact anyone they met today or start a group?
- Any aspects delegates would change? Anything missed out on reflection?
- Where do you all go from now, what will you do with this new information and skills?

Ask participants to fill out the feedback form and confirm people know how to claim any expenses.

Resources

- 'Action plan' [Resource 35] and 'Feedback forms' [Resource 36]
- Make sure participants know they can take away resources. Consider having a 'library' table where people can browse.

Resources

This part of the manual contains resources which can be used as worksheets or handed out as information to aid discussion.

Each resource is numbered and some are referenced in particular activities.

Each page has the following information on it:

#	P
Resource number	Page number (e.g. 1 of 2)

Creative Commons licensing information

The Creative Commons is is a nonprofit organization that enables the sharing and use of creativity and knowledge through free legal tools. We license using Creative Commons because of our belief in sharing learning and resources. If you are creating something new for this manual we encourage you to find out more at http://creativecommons.org/.

Please note, if you have any resources you think would be good to include, or any ideas, suggestions or corrections, please email research.learning@macmillan.org.uk.

Presenting, printing and using resources

All the resources in this manual have been designed so that they can be printed easily.

Printing is best done from the PDF version, although it is available in other formats such as Microsoft Word if you would like to edit or adapt materials.

In order to support people who may be printing and preparing materials we have also created a guide to what to print and how to prepare materials in the resource list.

This guide is based on the experiences of facilitators who have just started facilitating and are building up their own resources and developing their own way of delivering.

As a result, this can be thought of as a helpful starting point and a guide of things to have prepared and how it can be done.

Resource list

Resource title	Resource number	Module Title	Module number	Presentation and printing instructions
Types of research cards	0			Print and cut up into cards
Types of research blank grid	1	Research Methods and Terminology	4	
Blank definitions of research	2	Research Methods and Terminology	4	
Definitions of research	3	Research Methods and Terminology	4	
Applying research methods	3a	Research Methods and Terminology	4	Print single sided and cut questions up
Why research?	3b	What is research?	3	Print single sided
Cochrane and All Trials	4	Research Methods and Terminology	4	
Questions to ask about research	5	Research Methods and Terminology	4	
LOMA Phase II clinical trial advert	6	Communicating Research AND Current Research and Involvement of the Public	6 & 7	
A real example of a trial	7	Communicating Research AND Current Research and Involvement of the Public	6 & 7	
LOMA trial fact sheet Phase III	8	Research Methods and Terminology	4	
Global Daily News and a real article	9	Research Methods and Terminology	4	
Common terms	10	Research Methods and Terminology	4	

Creating an incentive for discovery	**11**	Research Funding	6	
'Group working (6Rs) and Answering important questions using Maslow's 'hierarchy of needs'	12	Group Working	9	Print double sided as hand out
Patient and public involvement	13	The Research Cycle and Lay Involvement	5	
Range of public and patient involvement	14	The Research Cycle and Lay Involvement	5	Printed handout or drawn diagram
So what did you do?	15	The Research Cycle and Lay Involvement	5	Print the signs from page 2/6 to 6/6 on the following pages for activity 2 'The range of public involvement'. Print on one side only. Consider laminating.
Research Cycle	16	The Research Cycle and Lay Involvement	5	Print the signs from page 1/10 to 10/10. Print on one side only. Consider laminating.
'What is research? Stories and facts about public involvement in research'	17	What is Research? AND The Research Cycle and Lay Involvement	3&5	Print for reference or as a handout
Translational research	18	Research Methodology and Terminology	4	
What did open data ever do for us?	19	The Research Cycle and Lay Involvement	5	

The public and the private interests - research and pharmaceutical companies	20	Research Funding	6	
Public involvement in research cycle	21	The Research Cycle and Lay Involvement	5	Print A3 and consider laminating
The Haldane Principle	22	Research Funding	6	
Research funding facts	23	Research Funding	6	
Helpful Questions	24	Current Research	8	
Up for discussion: Do not censor science in the name of biosecurity	25	Research Cycle	5	
Up for discussion: Can a hallucinogen from Africa cure addiction?	26	Research Cycle	5	
Up for discussion: Ministers deny GlaxoSmithKline claims of drug	27	Research Cycle	5	
'Recruitment Examples'	28	Recruitment Examples	10	One sided
Insight to Foresight	29	Recruitment Examples	10	One sided
Template Advert for Patients and the Public to get Involved in Research	30	Research Cycle	5	
Template Role Description for Patients and the Public	31	Research Cycle	11	
How to incorporate patient and public involvement in the research process	32	Research Cycle	11	
Ways of getting involved	33	Current research and involvement of the	8	

		public		
Who I met and what I want to talk to them about	34	Current research and involvement of the public	8	
Action Plan	35	Pass It On	11	
Climbing the Ladder of Involvement	36			
Knowledge and Skills Grid	37			
Funding Applications	38			
Untangling the Terms	39			
Engagement in Research Process	40			
Feedback forms	41	Pass It On	11	Print the four pages double sided, no need to staple
Visit us BRP online	42			

A. Research done in an environment (a laboratory) in which the team are able control and simulate clinical conditions or situations.

This research may include animal experiments or computer modelling.

B. Research that seeks to understand the experiences that people have in their lives. It captures knowledge that cannot always be counted in numbers.

It may be conducted by interviewing or observing people, using questionnaires or by reviewing case notes or diaries.

C. The researcher gains information about a particular problem or situation with the assistance of those who participate in the research.

It looks for solutions by carrying out 'an action' which is then reviewed to see whether it has addressed the problem. The process will be repeated until a satisfactory solution is found.

D. Research that studies a group of people who are free from disease but have been exposed to a potential cause of that disease.

These people may be compared with a control group that is similar but has not been exposed to the potential causal factor/s. Groups are followed up into the future to see what happens.

E. Research in which participants are randomly allotted or assigned to one of two groups.

One is the research group receiving an intervention, and the other is the control group receiving conventional treatment, no treatment or a placebo. Participants in both groups are monitored to see if any differences emerge.

F. Research that studies a group of people with a particular disease (an outcome of interest).

Researchers look back in time to see what those people may have been exposed to in order to identify possible causes of the disease. This is compared with a suitably matched but unaffected group.

G. A review of all the research studies that have been conducted into a particular topic where they have been systematically identified, appraised and then the results summarised according to pre-determined criteria.

This is usually carried out with randomised controlled trials but could also be used with other types of research studies.

H. A term used to define

research to test new treatments and diagnostic procedures for all diseases.

Research begins in the laboratory and covers all stages of experimentation up to and including transfer to 'first in human' clinical testing. Sometimes known as ''from the bench to the bedside''

#	P
0	1/1

Match the definitions to the letters

Action research

Systematic reviews

Randomised controlled trial

A case control study

Translational research

Qualitative research

Laboratory research

A cohort study

#	P
1	1/1

Fill in the types of research to match the definitions

A: ……..
Research done in a controlled environment in which the team are able to control and simulate conditions or situations. This laboratory research may include animal experiments or computer modelling.

B: ……..
Research that studies seeks to understand the experience that people have in their lives. It captures knowledge that cannot always be counted in numbers. It may be conducted by interviewing or observing people, through questionnaires or by reviewing case notes or diaries.

C: ……..
The researcher gains information about a particular problem or situation with the assistance of those who participate in the research. It looks for solutions by carrying out an action which is then reviewed to see whether it has addressed the problem. The process will be repeated until a satisfactory solution is found.

D: ……..
Research that studies a group of people who are free from disease but have been exposed to a potential cause of that disease. These people will be compared with a control group that is similar but has not been exposed to the potential causal factor/s. Groups are followed up into the future to see what happens.

E: ……..
Research in which participants are randomly allotted or assigned to one of two groups. One is the research group receiving an intervention, and the other is the control group receiving conventional treatment, no treatment or a placebo. Participants in both groups are monitored to see if any differences emerge.

F: ……..
Research that studies a group of people with a particular disease (an outcome of interest). Researchers look back in time to see what those people may have been exposed to in order to identify possible causes of the disease. This is compared with a suitably matched but unaffected group.

G: ……..
A review of all the research studies that have been conducted into a particular topic where they have been systematically identified, appraised and then summarised according to pre-determined criteria. This is usually carried out with randomised controlled trials but could also be used with other types of research studies.

H: ……..
A term used to define research to test new treatments and diagnostic procedures for all diseases. Research begins in the laboratory and covers all stages of experimentation up to and including transfer to ‘first in human’ clinical testing. Sometimes known as ‘’From the bench to the bedside’’

#	P
2	1/1

Some different types of research methods

A Lab research: the researcher has total control over the environment and what happens to the sample.

B. Qualitative Research: Is the room warm enough?, each of you will have a different answer depending on how you feel and if asked to judge it from 1 to 10 will probably have a range of answers.

C. Action Research: when the water was contaminated in a reservoir the scientists needed to work out how to destroy the bug and make the water safe again so they tried various ways of treating the water e.g. did that work, yes/no, why, try this, what did that do, try this, etc.

D. Cohort Study (forward arrow) the Chernobyl radiation leak. Those exposed to radiation have been monitored to see the effects alongside another similar group not exposed. The study is to see what are the effects of the exposure compared to the control group.

E. Randomised Control Trial: two groups of people, of a similar mix of age, sex, disease etc are compared when testing a new treatment on one group against the current treatment on the other. Randomization allows the results to be as impartial as possible. Most clinical trials are Randomised Controlled Trials (RCT's).

F. Case Control Study: a group of young asthma sufferers were investigated to see if living in a damp house affected/caused the asthma. Scientists looked back at the life of each child to see if they could identify similar conditions that would help them find a cause that matched most/all of them.

G. Systematic Review: Systematic reviews compare all relevant randomised controlled trials in health care or all comparable kinds of research. For example, in 1993 the Cochrane Collaboration led a review that compared similar research that had been done around the world to determine how effective giving steroids to premature babies was as all previous trials had been inconclusive. The review compared all similar trials and concluded steroids saved lives.

H. Translational research: Also known as ''from the bench to the bedside'' this describes the process of designing/discovering a treatment in a laboratory and then the process it goes through till it is tested on humans in clinical trials. You ''translate an idea into an action''.

#	P
3	1/1

*What **Research Method(s)** might be most appropriate **to find out…***

How a local support group would know if what they do makes any difference?

*What **Research Method(s)** might be most appropriate **to know…***

Whether any comparisons have taken place on existing research into a condition?

*What **Research Method(s)** might be most appropriate **to learn…***

How a new treatment be tested against the current treatment and carried out with large numbers?

*What **Research Method(s)** might be most appropriate **to realise…***

Whether exposure to the sun has any impact on Beach Volleyball players?

*What **Research Method(s)** might be most appropriate **to identify…***

How a scientific new drug development be tested with humans for the first time?

#	P
3a	1/2

*What **Research Method(s)** might be most appropriate **to comprehend…***

What does it mean in practical terms for people who are living with a particular disease?

*What **Research Method(s)** might be most appropriate **to discover…***

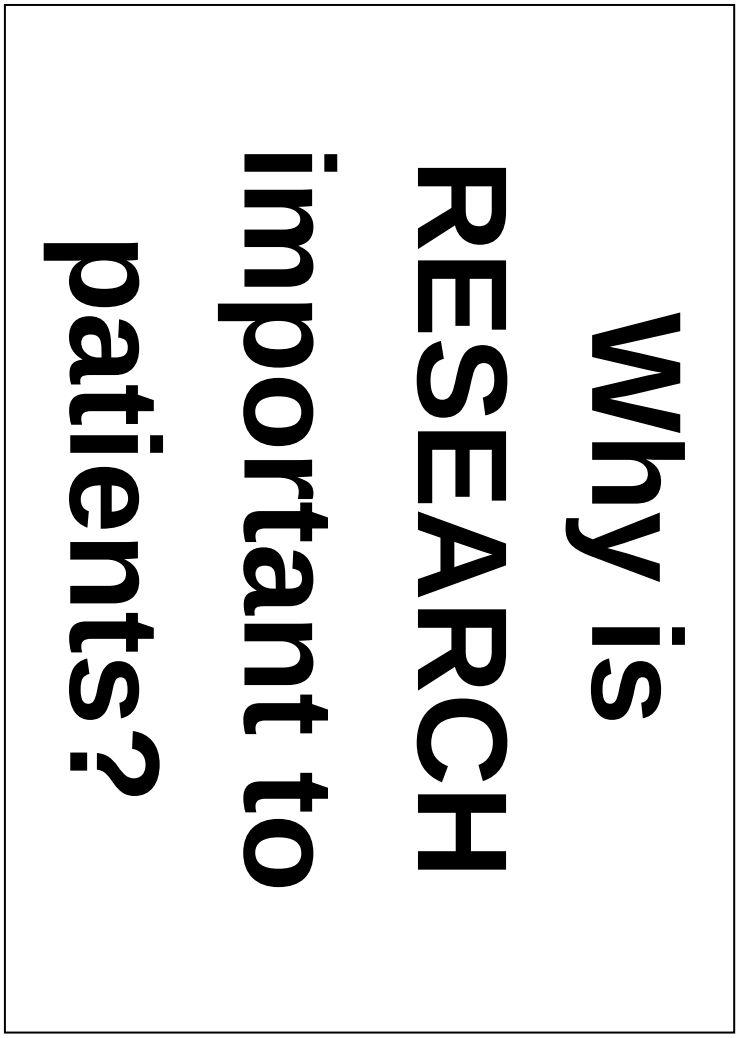
If a particular drug work when tested on samples of human tissue?

*What **Research Method(s)** might be most appropriate **to understand…***

How might we study and compare a group of people exposed to radiation (e.g. Chernobyl)?

#	P
3a	2/2

#	P
3b	1/4



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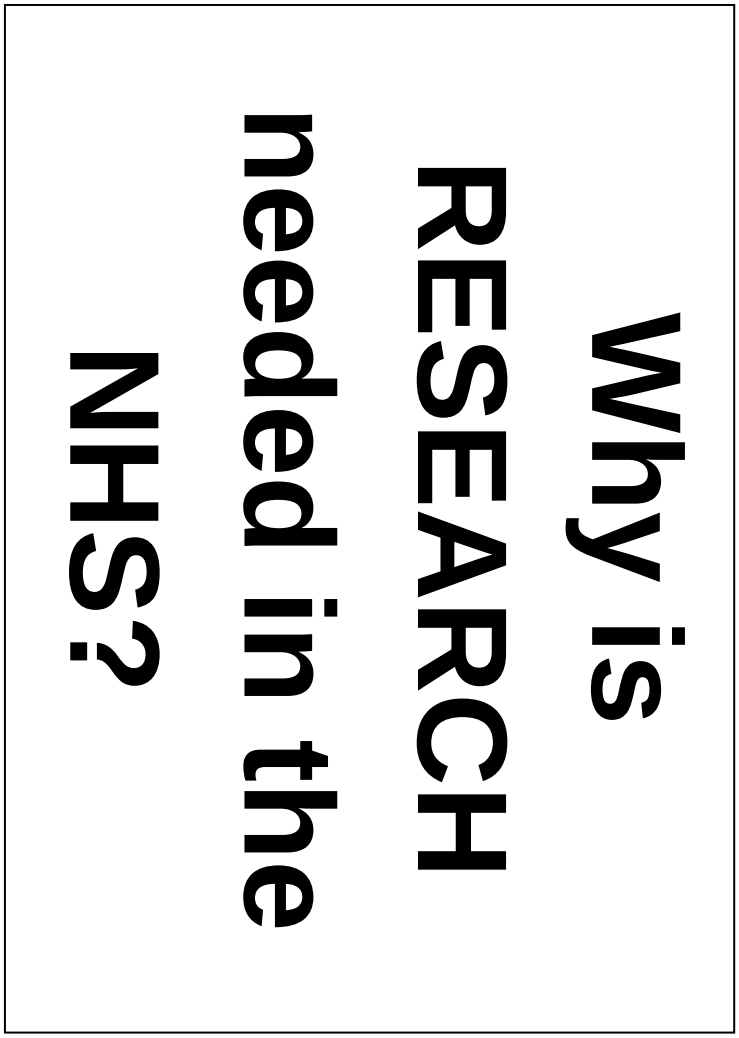
3b	2/4



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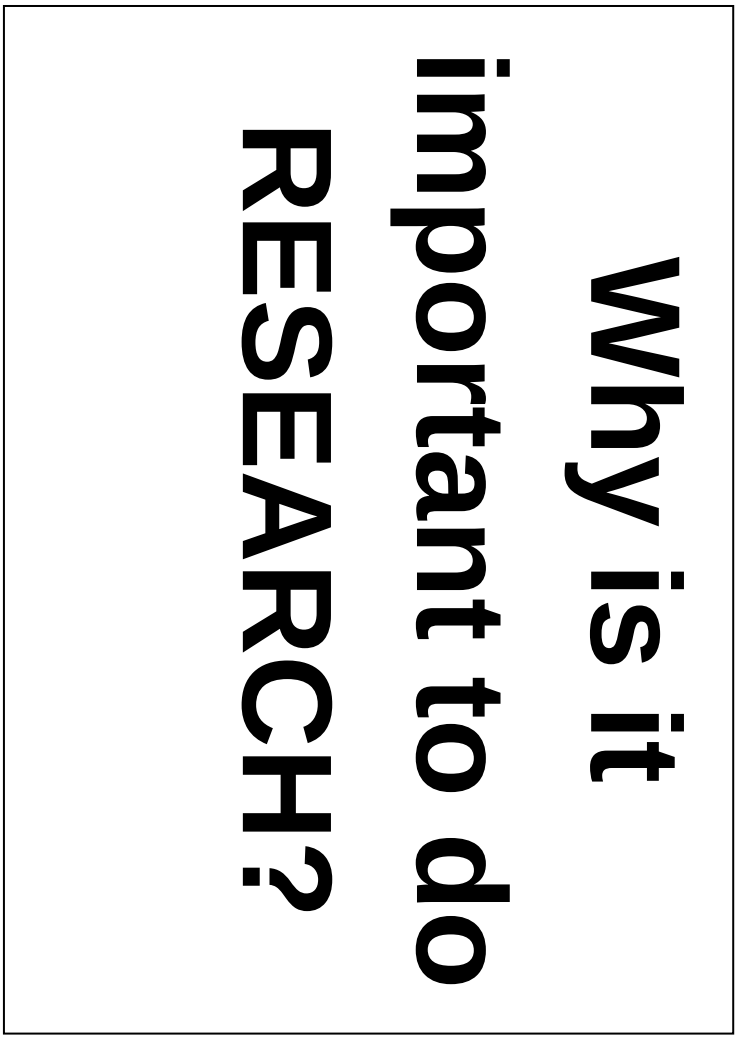
3b	3/4



#	P
3b	4/4

THE COCHRANE COLLABORATION®

#	P
4	1/2

The Cochrane Collaboration

The Cochrane Collaboration is an independent nonprofit organization consisting of a group of over 28,000 volunteers in more than 100 countries. The collaboration was formed in response to a felt need to organize research information in a systematic way. Such organization of information is required so that all information is reviewed before making a health care decision and so that there is a clear understanding where more research is actually needed.

The Collaboration aims to provide compiled scientific evidence to aid well informed health care decisions. It conducts Systematic reviews of randomized controlled trials of health care interventions and tries to disseminate the results and conclusions derived from them. A few more recent reviews have also studied the results of non-randomized, observational studies. The systematic reviews are published in the Cochrane Library.

The collaboration gained official relations with the World Health Organization (WHO) in January 2011 as a partner Non-governmental organisations (NGO's) and a seat on the World Health Assembly to provide inputs on WHO resolutions.

[Taken from Wikipedia – April 2012]

All Trials

Doctors need the results of clinical trials to make decisions about which treatment is best. Currently, drug companies and researchers are allowed to withhold the results of clinical trials from doctors and patients if they wish to, alongside other information.

Around half of all clinical trials have not been published; some trials have not even been registered.

This means that we are misled about the benefits and risks of treatments. We can be misled into prescribing an expensive new drug, for example, when in reality an older cheaper one is more effective.

Patients are harmed and money is wasted.

If action is not taken urgently, information on what was done and what was found in trials could be lost forever, leading to bad treatment decisions, missed opportunities for good medicine, and trials being repeated unnecessarily.

All Trials is a petition to get trial results published.

You can get involved by signing the petition, spreading the word, contacting your elected representative or writing to relevant organisations.

www.alltrials.net

#	P
4	2/2

Questions to ask about research

Questioning everything is at the root of scientific understanding, that's what gives us knowledge. Good research attempts to answers questions using a rigorous methods to give results.

Critical appraisal is a way of looking at published or reported research and asking questions about the validity of the methods and the results and how published findings can be acted on.

Below are some basic questions to ask of any research before it moves on from the design stage.

When answering these questions, try to start with what is good, and then move onto what could be improved

---

Ethics – Are the participants being recruited in an acceptable way? Is it possible to have informed consent? Are participants paid and is this relevant? Are participants exposed to unnecessary risk? Are the exclusion criteria appropriate or too excessive? (e.g. gender, age or being pregnant are common exclusion criteria)

Need – Does the research question address something of importance to the public and patients? Does it look at clinical need or an uncertainty about current treatment or services?

Public involvement – Do you think the public have been involved in identifying the need for the research, the design of this research or any other stages? Is there any budget for public involvement? Is there any evidence of public involvement?

Research method – is the research question clear? Is the method valid? Do you need more information to answer these questions? Is the research new or has it been done before (e.g. has a systematic review been done)?

Translation – is it clear how this research could be useful? If not, how could it be better explained?

Research Funding – Who is paying or this research, is there a conflict of interest? Is the cost of this research justifiable when compared with other priorities? Who owns the findings, data and the results (e.g. intellectual property)?

Dissemination - Will the results and data be published? Will this be publicly accessible? (this may help avoid research being repeated). Will any of the successes of involving the public be shared?

The questions below can be more helpful to ask for clinical research

Patient experience – what issues might there be? Will this potentially improve the experience of future patients?

Information – How is information presented to potential participants? What is good, what could be improved? Does this affect ability to give informed consent? Are the risks and benefits clear? Is the timescale and commitment clear?

For more detailed information on critical appraisal, find some free resources from the Critical Appraisal Skills Programme at:

http://www.casp-uk.net

#	P
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Love drinking?

Hate the morning after?

If the answer is 'yes' and you are a healthy, 14-95 year old, and do not suffer from hay fever or chronic diarrhoea **then you could help us!**

Get paid to drink as much as you can!

No hangover!

You'll help us prove we've found a **miracle cure that banishes hangovers!**

If you complete our trial* **we'll pay you** compensation of up to

£2000**

*Further trial information available on request ** Upon signing our full disclaimer document and buying our recognised insurance policy*** *** Insurance costs **only** £700 a year

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HEPATIC – Patient Information Sheet – Phase II clinical trial

#	P
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About the trial

The initial part of the trial will involve a 3-day 'party'. That's right!

We're inviting you to join us for an 'all you can drink' all expenses paid 3-day 'party'*.

What is it?

Hyper-enzyme polymerase action transmission inhibitor co-enzyme (HEPATIC) works by targeting the pathways in the multi-perplexion Maltbarely pathway. After ingestion into the alimentary canal, release through the hepatic portal vein transmits HEPATIC to the endocrine system, targeting the B52 receptors found on the Pilsner cells in the Laphroaig region of the liver. The HEPATIC compound works by inhibiting the active site of the hangoverase enzyme, which produces throb-clusters which enter the blood and attach to the gag-receptors in the brain and the back of the retina (further information on page 212). By inhibiting this enzyme, HEPATIC works by preventing the symptoms of hangover at the source.

More information about the trial

This phase 2 trial will take three years and involve 18 visits to your local trial centre. The centres are in Land's End, John o'Groats and the island of Sark. Each visit will require 2 pints of blood, a presentation of a week's worth of stool samples and 8 pints of urine (presented in a vessel of your choice). This research is being paid for by the Brewers Research Institute (BRI).The Brewers Research Institute is a company owned by the 'Teenage Alcopop Production Company'

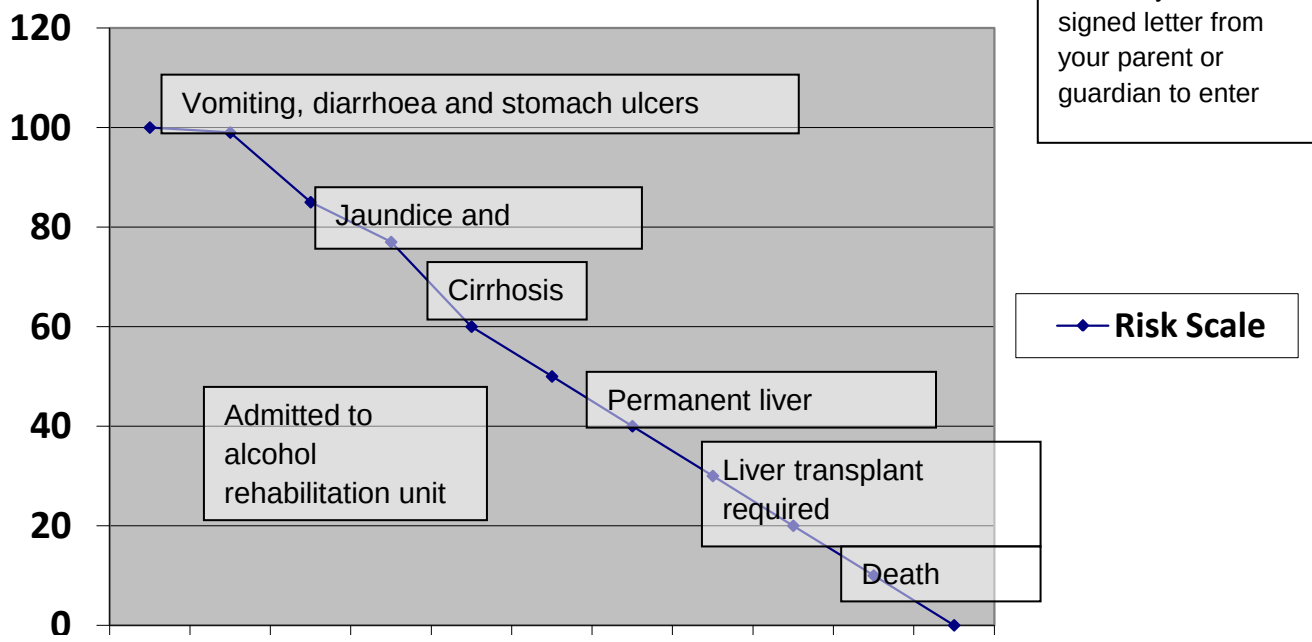
Pay

You will be paid after attending all 18 visits to your local trial centre. Please note that you can leave the trial at any point you like but you will not be paid and will be asked to contribute toward the cost of the drinks you have consumed.

Who can't join?

If you're under 14 or over 95 you'll need a signed letter from your parent or guardian to enter

Risk



*Please note that the word 'party' in this document refers to a controlled alcohol intake session, where participants will be given 4 units intravenously every 2 hours for a 48 hour period in isolation. Participants will be actively observed over the full 48 hour period.

Example trial recruitment – taken from 'CancerHelp UK' December 2013

A trial of mogamulizumab for peripheral T cell lymphoma

This trial is looking at drug called mogamulizumab (also known as KW-0761) for peripheral T cell lymphoma that has got worse or come back after other treatment.

Peripheral T cell lymphoma (PTCL) is a type of non Hodgkin lymphoma where blood cells called T cells become cancerous.

Doctors often use chemotherapy to treat PTCL, but sometimes it continues to grow, or comes back after treatment has finished. Researchers want to find new treatments to help people in this situation. In this trial, they are looking at a drug called mogamulizumab (pronounced mo-gam-u-liz-oo-mab).

Mogamulizumab is a type of biological therapy called a monoclonal antibody.

The aim of this trial is to find out how well mogamulizumab works for people who have already had other treatment for PTCL.

Recruitment

Start 04/07/2012

End 30/12/2013

Phase

Phase 2

Who can enter

You may be able to enter this trial if you

- Have peripheral T cell lymphoma that has come back or got worse despite having at least 1 other treatment that reaches your whole body (systemic treatment)
- Have lymphoma cells that make a protein called CCR4 – the trial doctors will test for this
- Have at least 1 area of lymphoma that can be seen and measured on a CT scan
- Are well enough to be up and about for at least half the day (performance status 0, 1 or 2)
- Have satisfactory blood test results
- Are at least 18 years old
- Are willing to use reliable contraception during the trial and for 3 months afterwards if there is any chance you or your partner could become pregnant

You cannot enter this trial if you

- Have lymphoma that has spread to your brain or spinal cord (the central nervous system)
- Have certain sub types of PTCL – the trial doctors can advise you about this

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- Have had chemotherapy, radiotherapy, immunotherapy or any other experimental cancer drug in the last 4 weeks
- Have not recovered from side effects of other cancer treatment, unless they are very mild
- Have had another type of cancer in the last 5 years apart from one of the following that has been successfully treated - non melanoma skin cancer, very early stage melanoma (melanoma in situ), carcinoma in situ of the cervix, ductal carcinoma in situ or lobular carcinoma in situ of the breast, or prostate cancer that was contained in the prostate gland (localised prostate cancer)
- Have lymphoma that has come back within 75 days of having a stem cell transplant using your own cells
- Have ever had a stem cell transplant using cells from a donor
- Have ever had a skin condition called psoriasis, unless it was very mild or only affected a very small area of your body
- Have already had mogamulizumab (KW-0761)
- Have had an allergic reaction to another monoclonal antibody or similar type of drug
- Would need to take steroids during the study, or currently take other drugs that damp down your immune system – the trial team can advise you about this and it is important you don't stop taking any medication without talking to your doctor
- Have had a heart attack in the last 6 months, have certain other heart problems or high blood pressure that cannot be controlled with medication
- Have an autoimmune disease such as rheumatoid arthritis
- Have any other condition that the trial team think could affect you taking part in this trial
- Are known to be HIV, hepatitis B or hepatitis C positive
- Have the herpes virus
- Are pregnant or breastfeeding

Trial design

This phase 2 trial will recruit about 35 people. Everybody taking part has mogamulizumab. You have it through a drip into a vein, once a week for 4 weeks.

If there are no signs of your lymphoma after the first 4 weeks of treatment (a complete response), you can have mogamulizumab twice a month for the next 2 months. After that, the trial doctor may suggest you carry on having it once a month.

If your lymphoma doesn't get any worse (stable disease) or gets a bit better (a partial response), you carry on having mogamulizumab. As long as you don't have bad side effects, you can have it once every 2 weeks for as long as it helps you. If your lymphoma starts to get worse, you will stop the trial treatment.

If your lymphoma gets worse during the first 4 weeks of treatment, you leave the trial. Your doctor will talk to you about other treatment options.

Hospital visits

You will see the trial team and have some tests before you start treatment. The tests include

- Physical examination
- Blood tests

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- Heart trace (ECG)
- CT scan

You may also have

- PET scan
- Bone marrow test
- Lymph node biopsy (the trial team might be able to use tissue from a sample of your lymphoma that has been removed in the past)
- Skin biopsy

The trial team will take photographs of your skin. It will not be possible to identify you from the photos.

You go to hospital once a week for the first 4 weeks of treatment. If you carry on having mogamulizumab for longer, you then go to hospital once every 2 weeks until you stop having the drug.

You have blood tests at each visit. And if you have a rash, the trial team will take more photographs.

During treatment, you have a CT scan every 8 weeks. You may also have more PET scans and bone marrow tests.

When you finish treatment, you go back to see the trial team and have more blood tests, a physical examination and an ECG. A member of the trial team will then contact you by phone to see how you are once a month for 3 months. You have blood tests every 3 months for up to a year.

Side effects

As mogamulizumab is a new drug, there may be some side effects we don't know about yet. The most common side effects that are known include

- A reaction when you have the drug that can cause symptoms such as back pain, high temperature (fever), headache, feeling sick, shortness of breath and low blood pressure
- A drop in blood cells causing an increased risk of infection, bleeding problems, tiredness and breathlessness
- Rash
- Changes to your liver
- Rapid heart rate
- An increase in your blood pressure
- A reduced amount of oxygen in your blood

If you develop a skin rash during treatment, the trial team will take more photographs. They will also take a biopsy from the area of skin where the rash is, and another from an area of normal skin. This is so they can check whether the rash is caused by your lymphoma or by the trial drug. If you do get a rash, you will have treatment for it.

Location of trial

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- London
- Manchester
- Southampton

For more information

Please note: we cannot help you to join a specific trial. Unless we state otherwise in this trial summary, you need to print this page and take it to your own doctor to discuss.

Find out how to join a trial or contact our cancer information nurses for other questions about cancer by phone (0808 800 4040), by email, or at

The Information Nurses
Cancer Research UK
Angel Building
407 St John Street
London
EC1V 4AD

Chief Investigator

Professor John Radford

Supported by

Kyowa Hakko Kirin Pharma, Inc

Updated: 29 November 2013

Taken from 'http://www.cancerresearchuk.org/cancer-help/trials/a-trial-of-mogamulizumab-for-peripheral-tcell-lymphoma' on 12th December 2013. Some formatting changed. Please note blue/underlined text links to further explanation on the website.

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Cocktail University Research department

LOMA trial fact sheet Phase III

Alcohol consumption

People vary in the amount of alcohol they consume before experiencing a hangover.

Subjects were entered into the trial when they had consumed at least the following amounts of alcohol. Men 6 units or more Women 5 units or more

Symptoms

A number of symptoms are associated with hangover:

Headache / Nausea / Shaky hands / Grumpiness / Spinning room / Dry mouth

Subjects were asked to score each of these on a scale of 1 (low) to 10 (high).

The hangover was counted in the trial if the subject scored 6 or more on at least 4 of these.

Allocation of the drug

Subjects collected their packet of hangover cure from the on-campus researcher if they reached the entry criteria. The envelopes were numbered, and half of them contained the new cure (LOMA pills) and half were harmless sugar pills with the same flavour. The envelopes were handed out in number sequence. The new drug and the sugar pills looked exactly the same.

Cure fact sheet

The treatment of the hangover was considered successful if the subject was capable of at least two of the following within two hours of taking the remedy:

• eating a Mars bar

• joining friends for a ‘morning after’ drink

• attending a morning lecture

• feeding the cat or dog without retching

• holding their own in a debate about any political issue.

Adapted with permission from an original idea developed by Crowe Associates.

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Read the 'The Moon on Monday' spoof article and then answer the following questions:

Questions:

- Would you be willing to take LOMA?
- What questions would you want to ask the researchers?
- Any other comments?

Taken from the 'The Moon on Monday' newspaper

Hangovers cured!

Party revelers will be leaping with joy after taking LOMA. Professor Bells of Cocktail University has released figures confirming the effectiveness of her department's new wonder hangover cure.

The brand name is yet to be decided, but LOMA (less of the morning after) is the front runner.

Professor Bells, blond, 39, has been studying the effects of the new drug over a period of time. She is confident that this drug, taken one hour before drinking commences, can banish those familiar symptoms of headache, dry mouth, shaky hands and grumpiness that follows 'over refreshment' of your favorite tipple.

When asked about the reliability of the results, Professor Bells remarked that the studies had been rigorously done and she herself had no hesitation in taking the cure (and had in face done so on a number of occasions).

As we are a paper for the people, we sent our roving reporter, Mike Sly, divorced, 42, on the streets of London to gauge the reaction of the common man.

'Brilliant' said Sam, 23. 'It's a license to get smashed'.

'I'm ecstatic,' agreed Bob, an off-license owner. But not everyone is impressed. 'I'm not sure about all of this,' said Crispin, 38, a health workers in the local health trust.

Taken from the 'The Moon on Monday' newspaper, a fictional publication.

Adapted with permission from an original idea developed by Crowe Associates

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Taken from the 'The Independent' newspaper

Hungover? There's a 'cure' for that as detox patch goes on sale

Christmas revellers have been offered a helping hand with an American hangover "cure" that claims to be second only to having an "intravenous stuck in your arm".

The Bytox Hangover Prevention Patch, invented by the US plastic and reconstructive surgeon Dr Leonard Grossman, has gone on sale in the UK following its launch in New York late last year.

According to the packaging, the patch replenishes the vitamins and acids lost when consuming alcohol, although it has not received any official medical backing either here or in the US.

It has, however, received glowing reviews from consumers who have posted on websites, with one writing: "I tried it twice. Both times after nine or 10 Martinis. I can only account for myself. It works great."

Users are instructed to attach the patch - which is similar in appearance and design to a nicotine patch - 45 minutes before drinking and leave it on until the next day or about eight hours after they finish drinking.

Dr Grossman has claimed that the ingredients - B vitamins, acai berry, vitamins A, D, E and K and folic - are delivered continuously to the bloodstream as opposed to those from a pill which are excreted relatively quickly.

Firebox, which is selling the patch in the UK, says on its website: "The rationale for this 'game changing' body patch is to stop hangovers before they start.

"Easily applied, it is infused with a powerful blend of vitamins, nutrients and antioxidants which are absorbed whilst imbibing, meaning a faster recovery time. American inventor Dr Leonard Grossman claims 'only an intravenous stuck in your arm while drinking could be more effective than a Bytox patch'."

It adds: "It won't however prevent you getting drunk and definitely won't prevent embarrassing and/or regrettable behaviour."

Ben Redhead, product manager at Firebox, said: "Look, we'd never usually encourage excess partying but the Firebox team, armed with the Bytox Hangover Prevention Patch, are definitely intending to take it up a level this Christmas.

"And if the patch means more productivity at work the next day then bingo, we're not only helping cure hangovers but we're helping the economy too."

The patches cost £12.99 for a pack of five.

Josie Clarke Wednesday, 31 October 2012

Taken from: http://www.independent.co.uk/life-style/health-and-families/health-news/hungover-theres-a-cure-for-that-as-detox-patch-goes-on-sale-8269139.html on 16.4.14

#	P
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Common Terms

You may hear the following terms used often in research. Read the terms below and think about how these might be relevant to any kind of research you know about.

Term	Definition
Loss to follow up	Where there are no results from certain participants on a trial (e.g. People who leave a trial)
Exclusion/inclusion criteria	Any criteria that would include or exclude someone from research (e.g. gender or age)
Intervention	This word is often used to describe what the research is testing or trying out. It could be a drug, a new kind of treatment pathway or something as simple as a massage.
Trial arm	Trials might have multiple 'arms' which are groups which are being tested simultaneously. One group will always be the 'control' group. This group has nothing different done to them than a patient who is not participating in the trial – they will often give results similar to the baseline measure. With drugs, the control group may be given the 'placebo' (no intervention or standard treatment). Different arms might start interventions at different times. Sometimes, trial managers switch which trial arm patients are on. They may or may not know when this happens.
Blinding	This is where the participant does not know which arm of the trial they are on, but the clinician does. 'Blinding' is not always possible (e.g. research into the benefits of massage)
Double-blinding	This is where neither the participant nor clinician knows which arm of the trial they are on. Trial managers will always have records of who is on which arm, but may need authorisation to 'unblind' a patient.
Baseline measures	These are the 'baselines', 'starting points' or 'benchmarks' which are objective measures

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	which outcomes can be judged against.
Outcome measures	These are the outcomes that are measured at the end of the research, they must be the same as the baseline measures.
Confounding factors	A confounding factor is anything which might have influenced the trial that was unplanned. For example, 'everyone on the trial caught the flu during the trial' or 'there was a transport strike and people couldn't get in for bloodtests'. A confounding factor would not be something caused by the trial intervention.
Randomisation	This is where patients are randomly allocated to a trial arm. Imagine someone flipping a coin.
Sample size	How many people were involved in the trial
Bias	Bias is an inclination to present or hold a partial perspective at the expense of (possibly equally valid) alternatives. Good questions to establish bias are: • '**has all the raw data been published**, or just an interpretation of what the data meant?' • '**who has funded this research**? Would the result be favoured by the funder/ was this the predicted outcome?'

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Creating an incentive for discovery

Read this extract below:

Overall, tropical rain forests cover only about 6 percent of Earth's surface, but harbour more than half of its animal life and about two-thirds of its flowering plants, and most of this life remains unknown to us because too few researchers spend time in them. At least 99 percent of flowering plants have never been tested for their medicinal properties. Even now nearly a quarter of all prescribed medicines are derived from just forty plants, with another 16 percent coming from animals or microbes. There is a serious risk with every hectare of forest felled of losing medically vital possibilities.

From *A Short History of Nearly Everything* by Bill Bryson.

Now read the news story on the next page and think about the following questions:

- Who should pay for research into new medicines and cures?
- What are the advantages and disadvantages of anyone be able to 'own', 'patent' or 'copyright' naturally occurring cures, including genetic sequences?
- Should access to knowledge or research ever be restricted? What are the advantages/disadvantages of restriction? (e.g. medical journals like *The Lancet* which charge for access, 'commercially sensitive' research, military research such as biochemical weapons.)

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BBC NEWS

Thailand backs patent drug copies

Thailand's health ministry says it has approved the production of cheaper versions of patented anti-Aids and heart disease drugs.

Health Minister Mongkol Na Songkhla said the step was necessary to make the cost of the medicines - Kaletra and Plavix - more affordable.

The move was criticised by pharmaceutical companies but drew praise from Aids campaigners.

There are about half a million people living with HIV in Thailand.

"We have to do this because we don't have enough money to buy safe and necessary drugs for the people under the government's universal health scheme," Mr Mongkol told reporters. He said at current prices, Thailand could only afford anti-Aids medicine for a fifth of the country's HIV sufferers.

The minister said the move was permissible under international trade rules in the event of national public health emergencies.

Mr Mongkol said the cost of a generic version of Plavix, a blood-thinning treatment to help prevent heart attacks, would be about a tenth of the cost of the patented product. Plavix is sold by French-based Safovi-Aventis and US firm Bristol-Myers Squibb Co; Kaletra is produced by US-based Abbott Laboratories.

'Dialogue'

However the move has angered pharmaceutical firms, who said they were caught by surprise.

"They are concerned about continuing to invest in a country where the government cannot provide a basic guarantee for the safety of their assets," the Pharmaceutical Research and Manufacturers' Association (Prema) said.

But Aids activists welcomed the government's announcement. "It is a brave decision, despite both anticipated pressure from industry and possible threats to withdraw investments," said Kannikar Kijtiwatchakul, of aid agency Medecins Sans Frontieres.

"The authorities have engaged in dialogue with companies before, but the discounts have been marginal. The licenses will benefit a lot of people and will set an example to other countries who face the same problem."

Mr Mongkol said he was willing to negotiate with the pharmaceutical companies about importing their products at cheaper prices.

Story from BBC NEWS: http://news.bbc.co.uk/go/pr/fr/-/1/hi/world/asia-pacific/6310515.stm Published: 2007/01/29

#	P
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When working with others in a group or on a project, it can be helpful to make sure the following are as clear as possible:

Remit

- What is the purpose of the meeting/group?
- Are there any terms of reference? Does everyone have a copy?
- When they were last revised? Are they updated regularly?

Role

- Is each member clear about why they are there?
- What are people's expectations of you?
- Do you or others ever find that you have conflicting roles?
- What do others expect of you?

Representative

- Are you seen as a representative?
- If so, who are you supposed to represent? Do you have a constituency, a group of people whose views you aim to represent?
- How are you supported to be a representative? How might you gather people's views? How do you report back to them?
- Are you there because of a personal experience?

Responsibility

- What responsibilities do you or others have? (see terms of reference)
- Who sets the agenda? Is this responsibility shared?
- How are decisions made? How are they implemented? Who takes responsibility for reporting back and ensuring the wishes of the group are carried out?

Relationships

- Does it feel like being part of a team, everyone working together?
- Is there a sense of common purpose and goals?
- Do you get along with each other? Do you know each other as individuals or are you strangers brought together by your roles?

Readiness

- Are you ready to get involved? Have you considered your emotional readiness and any time commitments?
- Have you received any training to help you prepare for your role? Have you thought about how can you maintain and support your wellbeing?
- Do you know who or where you can go to for support regarding any of these issues?

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Answering important questions using Maslow's 'hierarchy of needs'

Maslow's hierarchy claims that needs that are **low** in the hierarchy must be partially satisfied before needs that are **high** in the hierarchy can be prioritised. Think of a hierarchy as a pyramid, 'low' meaning a basic foundation.

The answers to the questions on the left lie at the very heart of good meetings. They've been placed in an order to approximate to the hierarchy. Discuss whether you agree with the questions being placed with the associated needs?

1. Will this be a good use of my time? 2. Why are we meeting anyway? 3. Are we going to accomplish something? Will this meeting help me make a difference?	**Self Actualisation** To find self fulfilment and realise one's potential
4. Will we stay on the topic or go off at a tangent?	**Creative needs** To create symmetry, order, and beauty
5. Is there an agenda?	**Cognitive needs** To know, learn explore, find out
6. What's expected of me? 7. What happened as a result of the last meeting? 8. Will we be making decisions and if so how?	**Esteem needs** To achieve, to be competent, gain approval and recognition, self-confidence, independence
9. Should I be here? Am I welcome? Do I feel I am being treated with respect?	**Belongingness and love** To be loved, liked needed or accepted by others
10. Where are the fire escapes? 11. Who are the other people?	**Safety needs** To be free of danger physically and emotionally – a sense of security
12. When will we take a break (e.g. to go to the toilet)? 13. Where is the food? When will we eat? 14. How long will this take? When are we leaving? (Will I need a strong coffee or a sleeping bag?)	**Physiological needs** Food, water, shelter, sleep, excretion

High

low (basic)

Questions adapted from Roberta's Rules of Order by Alice Collier Cochran Published by 2004.

#	P
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Patient and public involvement

There are many things to think about when involving the public and patients in improving services – this document is intended to help ask the right questions for the right roles.

How to use this resource: Under 'Assumptions and barriers', read the questions and consider if these might be barriers to involving some people, and consider how you might overcome these. 'Learning needs and support' examines the role in more detail and asks questions about the support people might need support to develop.

Be clear what you want– do you want 'patient', 'user' or 'carer' involvement, a lay perspective or just anyone who can give their time? Consider who you might unintentionally exclude by using these terms and be clear what you mean by *engagement* or *involvement.*

Assumptions and barriers	Role Description	Learning needs & support
• What commitment do you expect (time/financial implications) • Have you asked people to think about their emotional readiness? • Do you expect them to be reading and writing information and documents? Have you considered what formats might be appropriate? • Are you assuming a good ability to speak and read English? • Do you expect a certain educational background?	**Lay Leader:** A person who speaks and acts on behalf of all members of the public, including patients and carers and who takes a leading role in representing other lay representatives. The role may involve holding people or organisations to account **Lay representative:** a member of the public (not a professional) who is a representative. They must speak and act on behalf of others. They may be guided by lay leaders but will be expected to take direct action to ensure that they are informed and able to represent the views of others.	**How are they supported to be a representative?** • How will they be gathering views? • Will this involve research? • Do they have a budget? • Should they be paid? • Is there admin and practical support (from an organisation?) • Is there any training available? **Who is already doing this?** • Are there any opportunities for them to be involved in peer support or have or be a buddy? • What can be shared with other organisations? (E.g. learning, resources) **How are people involved?** • Can people be involved in other ways? (e.g. is it face to face meetings? What can be done online, what cannot?)
• Are the people who have engaged with you the only people who might be interested?	**Interested and engaged members of the public:** People who know about and/or are interested in decisions being made, but may take no direct action other than giving feedback, being involved in a public dialogue or signing petitions	**Could there be a need for translation?** • Are there any groups or organisations who could support with this? **Remember**: public dialogue is not fully 'representative' but can give a strong indication of how the public at large feels
• It is easy to assume that people who are not engaged don't want to be. Often they won't even know how they can contribute or be involved.	**Uninformed, disengaged or disinterested members of the public:** people who, for what ever reason, are not engaged, informed or interested in influencing decision making or shaping the future of health and social services.	**A majority of the population are in this category.** • What information or support might some people need to help engage them or move them into other roles? • What might make people move back into this role? (e.g. not seeing direct improvements, or too much of organisational change?)

Remember: roles are not always fixed, they are often just a way of articulating different things people can or should do. Tasks can be more focused. There is always a way for dedicated people to give their time and develop their skills, what ever the label or role description

#	P
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So what did you do?

Involvement can range from going to ‘Llareggub’ (a fictional Welsh village created by Dylan Thomas – try reversing the name!), through to filling in a survey, joining a focus group, joining a committee to contacting (or becoming!) and elected representative.

This resource can be placed around a room to give people a chance to stand on the range of involvement and speak about what they have done.

#	P
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#	P
15	2/6

Filled out a survey

#	P
15	3/6

Focus Group

#	P
15	4/6

Join a

Committee

Minutes of last meeting

Matters Arising

Agenda…

Reading notes:

Was the remit of the group clear and were you given lots of reading and were you given plenty of time to read it and was it sent electronically and was it easy to read and did it make sense and did they use full stops and was it concise or did it often repeat itself and was the remit of the group clear and were you given lots of reading and were you given plenty of time to read it and was it sent electronically and was it easy to read and did it make sense and did they use full stops and was it concise or did it often repeat itself and was the remit of the group clear and were you given lots of reading and were you given plenty of time to read it and was it sent electronically and was it easy to read and did it make sense and did they use full stops and was it concise or did it often repeat itself ……

#	P
15	5/6

Did you contact an elected representative?

Did you try to become one?

#	P
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Identify topics

#	P
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Prioritise topics

#	P
16	2/10

Commission or fund proposals

#	P
16	3/10

Design research

#	P
16	4/10

Manage research

#	P
16	5/10

Collect data

#	P
16	6/10

Analyse and interpret data

#	P
16	7/10

Disseminate

#	P
16	8/10

Implement or translate findings

#	P
16	9/10

Evaluate impact

#	P
16	10/10

Stories and facts about public involvement in research

Over the years of running this course, we have heard and collected these stories. Think about what these stories might mean and what you might learn from them. Please feel free to use them and add to them.

Why we involve the public – A researcher who spent his life researching arthritis was diagnosed with it towards the end of his career. He stated he'd spent his life researching the wrong thing. He was researching a cure when he should have been researching how to open jars. He should have been researching how to **live with** arthritis. The MS Society famously asked their supporters how they should spend their research budget and as a result they shifted their funding focus to curing **and** living with, rather than just curing.

Public involvement in participant information is an ethical issue

A 'Participant Information Sheet' (PIS) which had been through 'user testing' (involving the public to provide a lay perspective and improve it) produced a 'revised PIS significantly altered in its wording and layout'. This was compared with one that hadn't been revised. When given a written test, 66% of participants who read the revised PIS were able to show understanding of all aspects of the trial, compared with 15% of those reading the original version. Therefore the original PIS 'may not have enabled valid consent'. *(Reference Knapp et al. BMC Medicine 2011, 9:89 http://www.biomedcentral.com/1741-7015/9/89)*

All information needs to be as clear as possible – A man's 2 year old daughter was in intensive care with advanced leukaemia, doctors said she had a number of hours to live. While by his daughter's bedside, he was asked if he could leave the room for a moment and have a conversation. He was met by three doctors who sat him down at a table, all three on the opposite side to him. They wanted to recruit his daughter onto a research trial. He had to decide then and there if he would consent. He decided not to, because it felt too rushed. His daughter is now ten and doing well.

The public will be involved, one way or the other – A researcher who was leading a research trial into gene therapy on the back of the retina. While carrying out the trial, participants formed their own user group with no formal encouragement or financial support from professionals involved in the trial. They then began to give feedback to the trial organisers on how it was run and ways to improve it. this included changing the time of morning blood test appointments from 9am to 11am, as participants could then use their free bus pass. The result was that the trial retained many more participants, as the feedback made it more appealing to people involved. The researcher leading the trail was asked if they had written about the public involvement in their write up of the results. They said they hadn't, despite the fact it immeasurably improved the trial and quality of the results.

Know your audience - A Clinical Research Nurse based in Glasgow was doing quick study to work out how accessible local memory service appointments were for a individual living with dementia and their carers. The idea was to call the carer and ask them a few questions on the phone to help inform decisions on access. All the people being phoned had agreed to share their views for the study, but when the Nurse and her team set out to make the calls one afternoon, they noticed nobody was answering the phone, so they gave up. The next morning, everyone answered, and when they enquired as to why their calls had gone unanswered the afternoon before, a *very* common answer was "oh Countdown was on, so we don't answer the phone during that".

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Facts about public involvement in research

- Many trials fail because not enough participants are recruited.
- There are many examples of where public involvement has helped improve trial design, participant information and management. This helps ensure the trial is designed in a way which reflects understanding of participants' needs and can help improve recruitment.
- Grant bodies, such as the NIHR (National Institute of Health Research) were concerned at the failure rate and included a requirement to provide information about public involvement in every grant application.

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Translational research

Translational research is the basis for translational medicine. It is the process which leads from ‘’evidence based medicine’’ to “sustainable solutions for public health problems’’. It aims to improve the health, quality of life and longevity of the world's populations and depends on developing broad-based teams of scientists and scholars. They must work together to focus their efforts to link basic scientific discoveries with clinical investigation, and translating the results of clinical trials into changes in clinical practice. This whole process must itself be informed by evidence from additional research, which draws on social and political sciences.

The following definitions describe the three phases of research. See if you can put them in the right order.

Phase (X) research

Phase X examines how findings from clinical science, (already shown to be efficacious and safe), function when they are applied in routine practice. It thus addresses development and application of new technologies in a patient driven environment - where the emphasis is on real patients in real-life situations, where demographic factors and competing priorities modify clinical decisions, and treatment responses. This phase informs guidelines about needs, acceptability, effectiveness, and cost efficiency in ecological settings and policies to promote uptake for optimal management and resource use. During this phase, consumer research explores patients’ behavioural responses to interventions and provides important insights into compliance and quality of life; health economics adds the evaluation of cost effectiveness and cost avoidance.

Phase (Z) research

Phase Z is the research process that investigates and translates non-clinical (i.e. laboratory) research results into clinical applications and tests their safety and efficacy in a clinical trial. In the case of drug discovery and development, translational research typically refers to the translation of non-human research finding, from the laboratory and from animal studies, into therapies for patients. This is often called "bench to bedside".

Phase (Y) research

Phase Y adds the necessary information to convert treatments and prevention strategies, (already shown to be effective and cost-effective), into sustainable solutions. Thus governments can generate enduring evidence-based policies. These require different types of research processes to evaluate the complex interacting environmental and policy measures that affect susceptibility to disease and the sustainability of clinical and public health management and prevention strategies.

Questions to discuss:

- Can animal testing ever be ethical? If so, how? If not, why?
- Phase Y talks about different types of research to evaluate research. What kinds of research could this include? How could the public be involved?

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What did open data ever do for us?

The UK is leading the world on open data. Open data is publicly released raw data (for example all collected data, not statistics), often from the government or public services, which is made available to everyone so they are free to use or reuse it any way they like. While it can be read by individuals, for example in a spreadsheet, it is primarily designed to be 'machine-readable', so it can be inserted directly into computer programmes (written by those inside or outside government).

The government has made releasing open data a priority because:

1. It makes the government more accountable to citizens and strengthens our democracy (for example DFiD's aid tracker)
2. It brings us better public services (for example The Guardian's GCSE Schools Guide)
3. And it feeds economic and social growth (for example transport data intermediary Placr)

What brings open data to life is how people use it. And in the few short years since we started releasing it, there have been hundreds of examples. A few illustrative uses made of open data are listed below.

Taken from: http://data.gov.uk/blog/what-did-open-data-ever-do-us [30.1.14]

What is Linked Data?

Part of Sir Tim Berners-Lee's original vision of the Web was that it should also be used to publish, share and link data.

The Linked Data Web is not just about connecting datasets, but about linking information at the level of a single statement or fact. The idea behind the Linked Data Web is to use uniform resource identifier or URIs (these are like the uniform resource locators or URLs you type into your browser when going to a particular website) to identify resources such as people, places and organisations, and to then use web technology to provide some meaningful and useful information when these URIs are looked up. This 'useful information' can potentially be returned in a number of different encodings or formats, but the standard way for the linked data web is to use something called RDF (Resource Description Framework).

Taken from: http://data.gov.uk/blog/what-is-linked-data [30.1.14]

Consider how open and linked data might change the future of research

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The public and the private interests - research and pharmaceutical companies

Please note: *This section of text was written by Jack Nunn, Learning and Development Co-ordinator from Macmillan Cancer Support. It was informed by a programme on the BBC World Service called 'Future Pharma' from the series 'Global Business' and by discussions with colleagues in Biomedical Research Centres. A link to information about the BBC programme can be found here. At the time of writing it is possible to stream this programme from the website. This text is intended to be a balanced and fair appraisal of the future of pharmaceutical funding and the role that public involvement could play.*

Introduction

The long and complicated history of medical research and economics has brought us to a scenario where many people perceive that medical research is principally funded by three kinds of organisations. The first is Government, the second is pharmaceutical companies and the third are educational institutions and not-for profit organisations (e.g. charities). However, recent developments mean that these three kinds of organisations are increasingly seeing the benefit of cooperation and partnership working. It's a moral maze and crucially, it's the public who find themselves central to the entire process.

How did we get where we are?

Increasingly, the profits and returns that pharmaceutical companies used to make from findings are diminishing. This is partly because, in the past, traditional cures such as antibiotics provided a relatively high return on investment as they could be used across a wide spectrum. With the advent of specialised or 'personalised' medicine – which in some cases involves individuals' genetics, the ratio of development and return is lower. For example, compare gene-therapy to a dose of penicillin.

Simultaneously, there is a global trend for a greater demand on fewer resources for the health budgets of Governments and more pressure on charities to provide more for less. Add into this mixture the dichotomy of many educational institutions around the world who are independently funded and often seek revenue from their discoveries while attempting to maintain their crucial role in 'blue sky' research, where direct benefits are not always immediately obvious. The result is that each of these kinds of organisations are beginning to recogonise the need to cooperate and work together to achieve their separate goals.

Who should pay for research?

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At the heart of these new partnerships lie some complicated moral questions. If we start with the question of '*who is research for*' the quite obvious answer should be *'everyone'*. When you ask '*what is it for*' then similarly, it could be '*to improve the quality of life for everyone*'. If you ask '*who pays for it*' and '*who should access it*' the answers are much less clear.

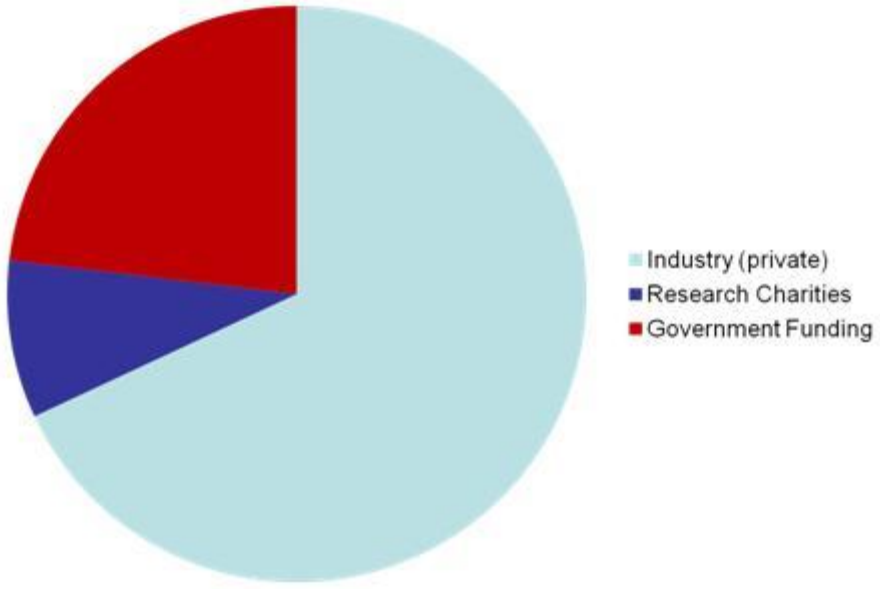
The remainder of this article is intended to examine this issue and attempt to articulate all sides of the discussion, while illustrating how and where the public will play a crucial role.

Should Governments pay?

The purpose of any Government should be to represent the needs of the people who elected them, who pay taxes to them and to be accountable to them. Ideally, Governments should also support the pharmaceutical industry to thrive in a sustainable and adaptable economic model which promotes good research. Most Governments in the world spend a relatively small percentage of the Gross Domestic Product on all kinds of research and development (including defense). The UK gave just 1.82% between 2007-2011 with Israel, Sweden and Finland coming in the top three with a range of 3.4 to 4.7%.

The UK spent 1.76% of its gross domestic expenditure on research and development (GERD) in 2010. Japan spent 3.17%, the US 2.54%, Germany 2.49%, France 2.26%, Italy 1.26% and Canada 1.93% (Taken from UK Government Statistics)

Of these percentages, health research makes up just a fraction. In 2011 the UK Government spent approximately £1700 million of tax-payers' money on health research funding. By comparison commercial funding (pharmaceutical companies) spend approximately £5000 million and charities around £650 million. That looks roughly like this:



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(For a more visual approach to Government spending, this resource produced by the Guardian visualises Government spending in Australia.)

This illustrates that while the Government plays a significant role in health research, they have never been, nor are likely to be the biggest funder.

Should commercial organisations pay?

When talking about commercial organisations and private companies the most simple way of defining them is that they are essentially accountable to their shareholders or anybody who has a stake in them. This means that their primary function is to give the people who invested in their company a good return (or profit) on this investment. A private company is one which does not have any Government or State ownership and is for profit. While they may have moral, ethical and legal frameworks in which they operate, the need to make profit is an inescapable part of the reality of pharmaceutical companies which must weigh in the balance of any actions or decisions they make.

The cost of bringing a drug to market in 1980 was about $180 million US dollars. In 2011 the figure is now $1.6-2 billion dollars. What has contributed to that cost is not the clinical trials, but the cost of every other drug that has failed to get to the 'market'. The UK's National Institute for Clinical Excellence (NICE) is one of the most respected institutions in the world when it comes to calculating the cost/benefit ratio of drugs and treatments. Many decisions that it makes impact on which drugs are bought by the NHS from the 'market' and have further implications across the globe on other Government's decisions. In some cases though, drugs are developed which NICE deems too expensive to justify. Commercial companies are starting to demand better guarantees at an earlier stage that their drugs will get to the 'market' and that there will therefore be a demand, thus reducing their investment risk. One of the best ways of doing this is for them to directly involve the public (or consumers) in the process of research and design, to ensure it meets a real need.

What alternative models have developed?

A new pattern is emerging for Governments, commercial organisations, charities and Universities to work together to research and develop novel treatments.

Rather than the traditional model of 'blockbuster drugs' being developed every few years, a model of developing a steady flow of smaller drugs which are highly targeted seems to be one option. One of the growth areas is certain to use genetic sequences and certain metabolic pathways to make treatments and products highly specific - not only to a certain condition, but to certain phenotypes within that condition. This will also mean differences in clinical trials.

The down side to this new economic model is that increasingly all stakeholders will

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be hesitant to invest in more ‘risky’ science and would rather put money where there is a guaranteed return on investment, or a directly measurable impact. This raises profound questions about at what point in the hierarchy of needs should the needs of patients and quality of life sit - against cost. If you're looking at what is effectively a free-market/ socialist model of development this is not a simple issue. More than ever the voice of the consumer needs to drive innovation so that real people and real issues speak louder than imaginary numbers.

The key part of this entire process is making sure the needs of the people are articulated clearly and given an equal weight to the needs of the shareholders and other stakeholders.

This is where public involvement is crucial.

I thought pirates were just at sea and online?

US researchers from the Fogarty International Center at the National Institutes of Health recently carried out some research which suggested that a third of malaria drugs used around the world to stem the spread of the disease are counterfeit. The researchers said that "Most cases are probably unreported, reported to the wrong agencies, or kept confidential by pharmaceutical companies,". Counterfeit drugs are dangerous and kill people. Pirated drugs are illegal copies of drugs made by people who do not have the Intellectual Property rights to do so. Aside from the countless casualties, both of these industries damage the profits of pharmaceutical companies. On the flip-side, many people can simply not afford the what pharmaceutical companies produce, and these markets reflect that gap. In some cases, Governments are now ignoring international intellectual property conventions and bypassing them in order to provide cheap drugs to their population. It’s a complicated problem that will only be solved by all sides working together.

New ways to advance

There are a number of new economic models developing in the face of a changing world. Some companies might adopt one or some of these strategies, while others might carve themselves up to become more adaptable.

Here is a summary of some ideas of the shape of things to come. While reading these, try to think of the advantages and disadvantages of each one.

Specialisation and focus
Research organisations should focus on what they do best, with areas of inquiry being shrunk into areas we have the best chance of winning - or seeing an impact.

Shrink portfolios and increase delivery

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Investment in Intellectual Property is shrinking. This is a hugely complicated area both legally and scientifically. Essentially though, even if it is possible to own the intellectual property of a new treatment or compound, it might not be enforceable and it is likely that it will be copied. This is especially true with genetic sequences, which could essentially be sent electronically in text form. Rather than risk investing huge amounts in a discovery where there is no guaranteed return, companies would instead focus on special or narrower populations where there was a greater chance of the Intellectual Property returning an investment. A good example would be a drug sold to the NHS to target a specific part of the metabolic pathway of a developing tumor.

Become generic

At the other end of the spectrum from specialisation is the idea of diversifying and investing in over the counter medicines. Many companies are investing in 'generic' (no Intelletual Property) over the counter drugs, but are also buying the production line, so they control each stage. This will ensure that they are involved at every stage of the supply chain, from development to first human contact. For example, if you can't patent toothpaste or a fizzy drink, make sure yours is the brand in every shop (and mouth) by whatever means possible.

Invest in developing emerging markets

The generic model is a particularly desirable one because 80% of the growth market for pharmaceutical companies is outside of America and EU. The pharmaceutical industry is also recognising the importance of improving and increasing access for patients for treatments and products in emerging markets. By creating a demand in a market which has not yet been developed (the developing world and their emerging markets) then this increases the reach. It also has the potential to grow revenue gathered from Intelletual Property if there are more people accessing it in a shorter period of time. However, this does pose interesting philosophical questions about how much the pharmaceutical instrustry should be investing in health care in the developing world. China is paying for roads and railways in India and Thailand so that they can create newer more efficient export markets. Should the pharmaceutical industry be contributing to paying to lay the rails into these new markets, rather than Governments alone? There is a conflict here though. Let's use vaccines as a hyperbolic example. They are hugely effective at preventing diseases, yet in an economic development model, why would pharmaceutical companies want to invest in a market which would see a single use vaccine used once, and only have a return on that investment for a limited number of years. However, waiting for the market to mature (the conditions to develop) they could get a much higher return by selling generic drugs for people to manage symptoms that could have been prevented by a vaccine. This is an extreme and fabricated example, but it's an attempt to illustrate that there is a direct conflict between the interest of shareholders and the interests of the people (and therefore the Governments who represent them). The conflict needs to clearly articulated and the real needs of the people and real and measurable

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universal human rights must always be elevated above the needs of shareholders and their artificial and imaginary numbers. Involving the public strengthens this voice.

Split up the company

Similar to the arguments for splitting up the saving and investment functions of banks, some argue pharmaceutical companies should take a similar approach. Profound questions are being asked, such as 'does it make sense for a toothpaste maker and a drug research company to be part of the same vehicle'. The internal rate of return (IRR) is how GlaxoSmithKline measures profit on certain income streams. They have improved their IRR on pharmaceutical research and development to 12% in 2012 from 11% in 2010. By comparison, over the counter drugs are 22% of the IRR. As far as investors are concerned, it's not always clear why to put incremental capitol behind pharmaceutical research, compared to a toothpaste which provides a much higher rate of return. These small increases in returns are what shareholders and investors are looking for. To extend the argument, should there be a company in existence which is torn between the demands of shareholders pushing them to invest in adding an extra stripe to their toothpaste, rather than ground-breaking research?

Crucially, many investors get returns of between 5-6% percent on investment in research, which is currently higher than interest rates. This still makes research an attractive long-term investment.

Collaborate

Collaboration between Government and Charity funded healthcare and pharmaceutical companies is essential, but the roles must be clearly defined and the priority must always be the improvement of the quality of life.

These collaborations are further complicated by the interactions of State institutions (which are paid for by the money of the people through taxes) which then subsidise or support the work of commercial companies in their research and development. In some cases, State institutions will share Intellectual Property with commercial companies.

The future of collaboration will not be 2-dimensional collaboration in a competitive 'first past the post' space-race style model. The future will be 'meta-collaborations' – an international space station or Hadron Collider style collaborations. These will exist between accountable Governments, academic institutions and their vast resource of great minds, large pharmaceutical companies with their efficient business models, and smaller bio-technology organisations with their unique experience and expertise.

A good example is neglected tropical diseases. Recently, a mix of companies, patient advocacy groups, Governments and Non-Government Organisations got together to tackle long neglected tropical diseases such as TB, Malaria, Dengue.

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They have come together to solve this problem and this is likely to be the future model. Pharma companies are taking a role in pulling academics together to look at solutions.

In this picture, it's also important to remember all the individual minds in the world who might not have access to ways of testing out their ideas. The story of the 15 year-old boy who had an idea for a cheap and quick test for early-onset pancreatic cancers and other cancers would not have been possible had he not had access to thousands of academic journals online, for free.

Conclusions - why the public must be involved

Everyone wins by improving public involvement in research, whether it's in the form of returns for the shareholders or better treatments and service available to the public. Perhaps, as we're talking about an economic model here, there is also a chance to see more involvement being recognised financially, with people's time and expertise being valued.

The future of research depends on collaboration and it's likely to be the platform upon which new discoveries will be made. However it is done in the future, patients and the public should be at the centre. Patients can give to commercial companies by being involved in development and other kinds of collaboration. This collaborative working can also help bring sustainable development and ensure research is meeting a need. This will reduce costs for bringing drugs and treatments to the market.

Most radically, research must begin to be perceived as something owned by everybody, paid for by everybody and for everybody.

This shift in thinking is reflected in organisations such as UK PUBMED. This is an on-line database that offers free access to a vast and growing collection of biomedical and health research information which has been paid for by public money. In a future where all data is shared data, linked data and open data, research will truly begin to be for the people and by the people.

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Public involvement in the **research cycle**

Evaluating impact

Why: By evaluating the impact of research and public involvement in research, you can help to build an evidence base and let others know about what worked well and what

How- involve the public in:

- How you are going to monitor and evaluate the impact of the research, and the public involvement in the research!
- Writing up (and publishing) an evaluation of the public involvement itself!

Example: The UK Clinical Research Collaboration published a report of a project to evaluate patient and public involvement in research.

Identifying and prioritising

Why: Involving the public in helping to identify and prioritise research allows them to influence what will be researched and lets researchers check that research priorities are the same as those of people who have the conditions being researched or who use relevant services.

How: use a mixture of face to face and online tools to facilitate discussions with existing reference groups and networks. This can include inviting the public to an event or researchers attending public and patient forums and events

Example: The James Lind Alliance facilitates Priority Setting Partnerships. These partnerships bring patients, carers and clinicians together to identify and prioritise the treatment uncertainties which they agree are the most important for research.

Commissioning

Why: Many funding organisations now involve members of the public in commissioning research. This gives a broader perspective to the review process, by considering the issues that are important from a public perspective.

How:

- Involve members of the public in reviewing research proposals
- Have a members of the public on research commissioning panels or boards
- Research grant applications
- Organisations representing groups or conditions commissioning research.

Example: After asking people affected by multiple sclerosis, the MS Society decided to fund research into improving the day-to-day lives of the people it affects, as well as biomedical research.

Designing and managing

Example: The 'Workplace Impact of Supported Employment Study' involved service users in the design of study through a local group. The purpose was to investigate the impact of Individual Placement and Support in a mental health catchment area.

How- involve the public in:

- Reviewing proposals and commenting on any potential difficulties in the design
- Developing research tools, information such as questionnaires, patient information sheets and consent forms
- Monitoring and managing the research process
- The selection process of staff and

Why: Involving members of the public in the design of research helps to ensure that the research is relevant to the needs of people, helps ensure the research question and outcomes are clear and ensures the research method has thought about the needs of anybody participating in the research.

Undertaking

Example: The Macmillan Listening Study trained people affected by cancer to carry out research to identify the cancer research priorities of people affected by cancer

How- involve the public in:

- Gathering and reviewing documentary evidence
- Carrying out interviews and running focus groups
- Developing research tools and information
- Analysing and interpreting the data or results of research.

Why: Involving members of the public in undertaking research can mean that research is carried out by people with a personal experience of the area of research or with relevant knowledge of a particular culture.

Analysing and interpreting

Example: The University Of Western Australia founded a programme to support researchers, consumers and the community to work in partnership to make decisions about research development using linked data.

How- involve the public in:

- Interpreting and commenting on results
- Analysing publicly available open data

Why: Publishing linked data and results in the public domain allows others to analyse any findings and facilitates a range of people to give their time, scrutiny and perspective to the research

Disseminating

Why: Dissemination is critical is the knowledge gained from the research is to have an impact. Good dissemination can also help identify the need for further research in a particular area.

How- involve the public in:

- Developing the dissemination plan
- Summarising the research findings in clear and accessible ways
- Presenting at conferences, speaking to patients, support groups and service providers
- Publication in **open access** peer-reviewed scientific journals
- Publishing on websites, writing to journalists, creating leaflets for waiting rooms or community centres.

Example: The Eve Appeal sent a letter to everyone who took part in the UKCTOCS screening trial and offered them the chance to continue to receive updates.

Implementing

Why: Members of the public involved in research are often passionate to ensure that action happens as a result of the research and are often able to establish relationships with key agencies and policy makers.

How – Work in partnership to plan the implementation as early as possible.

Example: Service user researchers and a nursing researcher co-delivered training in therapeutic interventions to staff teams in a mental health trust (St George's, University of London)

The Haldane principle

The **Haldane principle** is the idea that decisions about what to spend research funds on should be made by researchers rather than politicians.

History of the Haldane Principle

The 'Haldane Report' was written in 1918 and suggested that research required by government departments in the UK into general research, and research required by specific departments.

It recommended that **general research** should be under the control of autonomous Research Councils, which would be **free from political and administrative** pressures that might discourage research in certain areas.

The principle of the autonomy of the research councils is now referred to as the Haldane Principle. The first research council to be created as a result of the Haldane Report was the Medical Research Council.

Criticisms

- In 1939 J.D. Bernal argued that social good was more important than researchers' freedom in deciding the direction of research.
- Solly Zuckerman criticised it in 1971 for its artificial separation of basic and applied science, and the consequent elevation of the status of the former.

Discussion

- To what extent do you think the principle is applied in practice?
- Do you think research autonomy is important?
- Do you think researchers should control spending, or should there be more explicit involvement of the public? What are the advantages and disadvantages of researcher led spending?

Information taken from Wikipedia [http://en.wikipedia.org/wiki/Haldane_principle] on 5.2.14

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Research funding facts

Here are some facts about research funding in the UK.

When reading through this document consider if you think **more** or **less** should be spent by respective organisations. Consider how the public are involved in any of these decisions.

Please note that public figures on spending are approximately 3 years behind real time.

Government

- Government funding comes from a variety of bodies depending on where you live in the UK.
- From 2010-11 the UK spent £3.2 billion on research and development, with the Medical Research Council receiving £679 million and the Department of Health (including the NHS and National Institute for Health Research) spending £786 million. (Taken from UK Government Statistics)
- The National Institute for Health Research requires all research applications to give evidence of public involvement.
- Total public spending on science in 2010–11 was £161m. (Taken from scienceogram.org)
- The UK spent 1.76% of its gross domestic expenditure on research and development (GERD) in 2010. Japan spent 3.17%, the US 2.54%, Germany 2.49%, France 2.26%, Italy 1.26% and Canada 1.93% (Taken from UK Government Statistics)

Charity

- Third Sector (charity) funding is diverse. The Association of Medical Research Charities (AMRC) represents 123 member charities, who spend over £1.2bn a year on research. The Welcome Trust spends the most at over £500 million a year with charities such as Cancer Research UK spending £332 million on cancer research (financial year 2010/11). Two thirds of the total charitable spend on research is from the top two charities, with the remaining third coming from the other 121 charities.
- The Joseph Rowntree Foundation spends £10 million a year on its research. They focus on social policy research and development. It seeks to understand the root causes of social problems, to identify ways of overcoming them, and to show how social needs can be met in practice. It has a particular focus on poverty and the social determinants of health.

Industry (share-holder funded)

- Most research conducted in the UK is paid for by share-holder funded organisations from areas such as the pharmaceutical industry.
- Public involvement is not mandatory for private research, but many in the industry do involve the public, or would like to improve how this is done.

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Helpful Questions

I keep six honest serving-men
(They taught me all I knew);
Their names are What and Why and When
And How and Where and Who
(*Kipling)*

The right question at the right time, used in an appropriate way, can be a powerful thing. Here are some helpful questions organised into categories:

Asking for Information

- Could you please expand on that……..?
- Could you give me an example?
- Could you tell me a bit more about that?

Asking for clarification

- Are you saying that……..?
- Can I just be clear about…….?
- Do you mean……?

Specification

- How often does it happen?
- Who else does that/ is doing this?
- What exactly happens?
- When did it start?

Challenging questions

These should be used only when you have developed a trusting relationship:

- Could you please tell me how you think patients or the public might benefit from this research?
- I'm wondering how the patients and carers might feel about ….?
- Do we know what patients have said about that aspect of research?
- How do you feel you may have contributed?
- What would you have liked to have happened?
- What stops you?

Challenging behaviour

Here is a helpful way to challenge someone's behaviour which avoids direct confrontation:

1. **Label the behaviour not the person** – 'When you said/did that...'
2. **Label your feeling** '..that made me feel…'
3. **Ask them for the solution** 'I was wondering what you think the best way forward is?'

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Elaborate

This is to encourage a person to develop what they are saying:

- Would you like to say more about.....?
- Could you explain .....?
- Do you want to tell me more about.....?
- Can you give me an example of .....?
- Could you develop that idea?

Inviting different opinions

- I notice that you were frowning when we were discussing x…… and I'm wondering what that might be about

Encouraging full participation

- We haven't heard from you yet and I would value her perspective on this…..

Asking for opinions

- What would you do differently another time?
- What do you think would be the best option?

Focusing on feelings

- How do you feel about? How did you feel?
- Can you describe your feelings when …? What was the worst/most frustrating part?

Hypothetical questions

These are useful for getting the person to think about the future:

- How do you think that participants would react?
- How do you think that you would manage …?
- What resources would you use to deal with this?

Questions to draw on skills and resources

Questions can be used to get the person to think about the strengths that they possess and to find their own solutions:

- What has worked well in the past?
- Is there anyone who can support you?

Explore issues more fully

- Are there any other issues we should be thinking about here?
- Is there anyone who we haven't involved that we should have?

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Up for discussion?

Read this article and think about or discuss the following:

- What is the main idea of the article?
- Do you agree? Do you disagree? Why?
- If you agree or disagree, can you think of any arguments to support the opposing idea?

Do not censor science in the name of biosecurity

Security officials should not be concerned about the publication of mutant-flu research, says bio-weapons expert Tim Trevan.

The recent controversy over research into mutated versions of the H5N1 flu virus has focused on biosecurity concerns. It is easy to get the impression that this debate has created a clear split between a scientific community that wants the research to proceed and the results to be published and a biosecurity community that doesn't.

As a member of this biosecurity community for more than 30 years — I was special adviser to the chairman of the United Nations weapons inspectors in Iraq and covered chemical and biological disarmament with the UK Foreign Office in both London and Geneva, Switzerland — I believe this to be a false dichotomy. The research should be published in full, as it will be this week.

In fact, I will go further and say that the whole concept of dual-use biological research that is 'of concern' is flawed. It is a dangerous distraction, an inappropriate hangover from nuclear-threat analysis. Almost all biological knowledge can be either misused or applied for good.

Those concerned about publishing full details of the mutant-flu work say that they fear the research will be misused to develop more-effective biological weapons. But who would want to use a live, highly transmissible, virulent organism as a weapon, and to what purpose? And would censorship stop them?

Censorship of the H5N1 papers would not have kept the genie in the bottle. Suppressing such papers or limiting access to their findings might even encourage proliferation by drawing attention to the risks and by provoking those researchers denied access to the results to seek to replicate them.

Can we prevent proliferation by controlling research? Certainly, researchers, institutional review boards and funders must consider the implications of proposed research from the outset and implement a full biosafety and biosecurity plan. Major efforts have been made in this area. But to deny funding to projects with clear scientific or public-health value, even if they have some biosecurity risks, will drive

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research to undesirable sources of funding and prevent valuable research from being done.

If the knowledge and the science cannot be contained, then what about access to the materials and equipment required to turn research results into weapons? The direction in which technology and scientific services are heading does not bode well for controlling proliferation in this way. Companies already make genes for mail order. Free gene-design software exists. DNA printers will probably be on lab bench tops within the decade. But it cannot be morally or politically defensible to prevent wide distribution of tools that are indispensable to public health and basic research.

Warfare and terrorism are not the only biological risks that confront humanity. There is an entire spectrum of risks, from natural and accidental to deliberate. We are mostly helpless to prevent the periodic creation of new deadly diseases. We know that we face regular flu pandemics and that some will be particularly deadly.

An analysis of the effect of carrying out and publishing such research must compare two factors. The first — the cost — is the risk that publication will lead to deliberate release, multiplied by the impact of the release, multiplied by the frequency of release. The second — the benefit — is the possible reduction in the 250,000–500, 000 annual deaths worldwide due to seasonal flu and the more than 12 million lives lost annually to other infectious diseases, among other public-health benefits.

Precise calculation is not possible, but the evidence strongly suggests that the increase in risk is quite small. The known benefits of addressing public-health challenges from nature will almost always far outweigh the potential and unknowable increased risk of misuse.

The bigger argument in favour of continued research into viral transmissibility and pathogenicity (the focus of the mutant-flu work) is that it will ultimately deter the use of biological weapons.

The best strategy to stop biological attacks is to make biological weapons unattractive by making preparedness and responses so effective that the consequences are no worse than those of a train wreck. Increased understanding of transmissibility and pathogenicity will enable countries to identify threats earlier, develop better vaccines, produce them more quickly and develop broad-spectrum defences to diseases. This will protect against both nature and warfare.

Extract of an article published in Nature [486, 295 21 June 2012 doi:10.1038/486295a] Downloaded on 13.2.14 from http://www.nature.com/news/do-not-censor-science-in-the-name-of-biosecurity-1.10854

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Up for discussion?

Read this article and think about or discuss the following:

- What is the main idea of the article?
- Consider the significance of this sentence: 'Usually, this money [for research] would come from big pharmaceutical companies but drugs like ibogaine offer little potential for profit.
- What research has been done into ibogaine? Who published it? Is there any potential conflict of interest?
- Do you think that a single blind study is a good idea?

Can a hallucinogen from Africa cure addiction?

BBC News, 13 April 2012

Since the 1960s a disparate group of scientists and former drug addicts have been advocating a radical treatment for addiction - a hallucinogen called ibogaine, derived from an African plant, that in some cases seems to obliterate withdrawal symptoms from heroin, cocaine and alcohol. So why isn't it widely used?

Ibogaine has been associated with 19 deaths and given it is largely unregulated, the actual toll could be much higher.

According to a report published in the Journal of Forensic Science, 14 of these deaths were due to pre-existing health problems.

In New Zealand, the only country to have regulated the drug, the medical advisory board Medsafe reported that "the number of deaths due to methadone, the most controlled substance, were a little higher that those associated with ibogaine"

Ibogaine is illegal in the US, France, Sweden, Denmark, Belgium, Poland, Croatia and Switzerland.In the UK, it is neither banned nor licensed.

The drug, derived from the root of a central African plant called iboga, had been used for centuries by the Bwiti people of Gabon and Cameroon, as part of a tribal initiation ceremony.

But it wasn't until 1962, when a young heroin addict called Howard Lotsof stumbled upon ibogaine, that its value as an addiction treatment was uncovered.

Lotsof took it to get high but when the hallucinogenic effects wore off, he realised he no longer had the compulsion to take heroin. He became convinced that he had found the solution to addiction and dedicated much of his life to promoting ibogaine as a treatment.

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As far as scientists understand, ibogaine affects the brain in two distinct ways. The first is metabolic. It creates a protein that blocks receptors in the brain that trigger cravings, stopping the symptoms of withdrawal.

Its second effect is much less understood. It seems to inspire a dream-like state that is intensely introspective, allowing addicts to address issues in their life that they use alcohol or drugs to suppress.

In most other countries it remains unregulated and unlicensed. Lotsof set up a private clinic in the Netherlands in the 1980s and since then similar clinics have emerged in Canada, Mexico and South Africa.

These clinics operate in a legal grey area. But a small group of scientists is still working to bring ibogaine into the mainstream.

In the early 1990s, Deborah Mash, a neuroscientist and addiction specialist at the University of Miami, came upon the work of Dr Stanley Glick, a scientist who had researched the effect of ibogaine on rats.

Glick hooked rats on morphine, an opiate painkiller, by allowing them to self-administer it through a tube. He then gave them ibogaine and found they voluntarily stopped taking morphine.

Measuring success scientifically with addiction is problematic - addicts can be clean for months or even years before relapsing.

Most existing addiction treatments were created as a by-product of other research. Methadone was initially developed as a pain killer for German soldiers during WWII. In the last 20 years, only one new drug has been developed for opiate addiction.

Buprenorphine, sold as Suboxone, is a substitute drug much like methadone but it can be subscribed by a doctor and taken at home rather than in a clinic
"The treatment of addiction is woefully poor in the western world," says Ben Sessa. "After about 150 years of study into alcohol addiction, abstinence rates after a year are no better than about 25%." For opiates, abstinence rates after a year are about 10%. In the UK alcoholism is estimated to cost the NHS about £3bn a year.

Mash was contacted by Howard Lotsof. They began working together and in 1995 secured full approval from the US Food and Drug Administration (FDA) to investigate its potential in humans.

But these tests cost millions of dollars, and Mash applied for five separate public grants but each one was declined.

Usually, this money would come from big pharmaceutical companies but drugs like ibogaine offer little potential for profit.

It only has to be taken once, unlike conventional treatments for heroin addiction such as methadone which is a substitute and addictive itself.

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"One very cynical reason they are not being developed is that there is no patent on these drugs anymore so there is no pharmaceutical company involvement," says Ben Sessa.

Pharmaceutical companies make money by patenting new chemicals but ibogaine is a naturally occurring substance and is difficult to secure a patent on.

It also comes with some risks. Ibogaine slows the heart rate and when administered to rats in very high doses, it has been proved to damage the cerebellum, a part of the brain associated with motor function.

After failing to get funding, Mash opened a private clinical research centre on the island of St Kitts in the Caribbean in 1996. There she collected data on 300 addicts detoxed through ibogaine.

She says all patients showed an effect on their addiction, 70% went into remission for several months and many for years.

Determined to bring the treatment to more people, Mash is now working with the private sector to create a version of the drug that will be more attractive to pharmaceutical companies.

"Radical options are needed," says David Nutt, head of the UK's Independent Scientific Committee on Drugs, but he maintains some scepticism about so-called wonder cures.

"The history of medicine is littered with people doing interesting, challenging things, but when you do proper control tests they reveal a massive placebo effect," he says.

What is needed, he says, is a single blind study in which one group of addicts takes a standardised dose of the drug and another group takes a placebo, both followed by a full 12-step detox treatment plan. He estimates that would cost about $2.37 million (£1.5 million).

She is working to isolate noribogaine, a substance created by ibogaine in the liver, which she believes is responsible for inhibiting cravings, taking away the hallucinogenic effect. But she continues to push for research into the whole drug.

Dr Anwar Jeewa would like to see the drug licensed but says people need to understand its limits.

"Once you have a patient that is drug free and whose brain is back to its full potential then you can help them change their lifestyle," says Jeewa.

"Ibogaine helps to interrupt addiction but it's not a cure or a magic bullet," he says. "It has to be taken in the right setting and treatment has to be followed up with psychosocial care."

The text above is a extract from an article downloaded on 13.2.14 from http://www.bbc.co.uk/news/magazine-17666589

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Up for discussion?

Read this article and think about or discuss the following:

- What are the main points in this article?
- Do you agree or disagree with any side? Why?
- If you agree or disagree, can you think of any arguments to support the opposing idea?

Think about:

- What is in the public interest? What is not?
- Who is acting in the public interest? Who is not? Why?
- How could public and patient involvement improve this situation?

Ministers deny GlaxoSmithKline claims of drug delays

BBC News, 25 February 2012

Sir Andrew Witty from GSK said drugs were being "systematically delayed" from introduction and reimbursement

Ministers have rejected claims by the UK's biggest drug firm GlaxoSmithKline that new cancer treatments are being delayed to save money.

"Strategic thoughtfulness" was being lost in the "stampede" to cut costs, GSK chief Sir Andrew Witty said.

It was a Europe-wide problem as governments coped with austerity and got more anxious about debts, he added.

But the Department of Health said the approval process was getting faster and it had increased spending on new drugs.

Mr Witty, the head of the pharmaceutical giant, told the BBC: "We're seeing oncology drugs being systematically delayed from introduction and reimbursement. We're seeing a variety of the more innovative, and yes more expensive medicines, being delayed in a whole series of different diseases across Europe. Ultimately it's one of those situations where the drift will be imperceptibly happening, but when you look back in five or 10 years, a huge gap will have opened up."

He also said the government had cut prices by 5% a year as it got more and more anxious about its debt position - costing the firm £300m a year.

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New drugs are referred to the National Institute for Health and Clinical Excellence (Nice) by the government, where their cost-effectiveness are assessed.

'Increased health spending'

The DoH said the government had increased spending on health, including new drugs, with thousands more patients getting access to the most advanced treatments.

"The need for careful assessment of drugs' effectiveness by Nice is particularly important for patients and taxpayers during a time of economic austerity," it said."The government has not changed any assessment processes relating to cancer drugs. Furthermore, drug companies need to look hard at the high costs they are asking of the health service for their latest treatments."

But Prof Jonathan Waxman, professor of Oncology at Imperial College London, said Nice had blocked a number of new cancer drugs offering "significant benefits" to patients. "Unfortunately, the committee that regulates their availability in the UK has ruled against many of them," he told BBC Radio 4's Today programme. "And they've ruled against them on the basis of what many oncologists, many doctors, many cancer doctors believe are unfair grounds."

Shadow health secretary Andy Burnham also accused the prime minister of breaking his general election commitment to cancer patients.

"With a great fanfare, he said he would deliver quicker access to drugs for cancer patients," said Mr Burnham. Today we hear that his government is in fact delaying new treatments to save money. If true, this is a shameful state of affairs and a false economy. The prime minister must be kept to his pre-election promises."

But Alan Maynard, a professor of health economics, argued drug firms were demanding much higher prices than were reasonable, and the economies were justified.

"Nice are looking for good evidence and the industry is rather poor in doing good trials and telling us about the full effectiveness - which is often marginal. I think it's quite inevitable that in a period of austerity there will be downward pressure on the introduction of new drugs that are not demonstrably good in terms of improving patient health and which are extraordinarily expensive."

GlaxoSmithKline reported pre-tax profits of £1.9bn during the three months to the end of December 2011, up from a £193m loss during the same period in 2010.

For the whole year, the firm reported pre-tax profit of £8.2bn, up from £4.5bn in 2010.

The text above is a extract from an article downloaded on 13.2.14 from http://www.bbc.co.uk/news/uk-17163958

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Recruitment Examples

Dentures Study (Sue Pavitt)

This study was failing to recruit when someone suggested talking to people who were perhaps more likely to wear dentures. A discussion group at a care home was arranged and people said they would be interested in taking part. However when it was explained that the accrual times were first thing in the morning, the participants pointed out that they couldn't use their travel passes.

Question: What is the value of targeting a SPECIFIC GROUP and how might you go about identifying and involving them?

Diabetes Studies (Mela)

A member of the Diabetes Clinical Research Network was also a member of a London Mela organising committee. The Network arranged to have a stall, provided blood tests and sought people's views about research priorities.

Question: What is the value of considering WHERE you talk about your research and how might you go about making local links?

Mental Health (poster that was changed)

The information about a study was provided on a poster in the waiting area yet it failed to recruit. The researchers brought together a small focus group to discuss the issue and found out that the patients didn't think that the poster properly conveyed what the research was about.

Question: What is the value of thinking about LANGUAGE and how might you involve people in helping design your information?

Dementias (carers training)

Carers of people with dementia were concerned that the way studies were explained were often confusing and at times excluded the carers. They organised and delivered training for the professionals to help them.

Question: What is the value of getting people's views about COMMUNICATION and how might you go about involving them?

Cancer (often after diagnosis)

Too often people are still trying to cope with the diagnosis of cancer before being asked to take part in research. Many patients who have got involved in particular studies have become advocates and ambassadors for research.

Question: What is the value of having PATIENT AMBASSADORS and how might you go about involving them?

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Insight to Foresight

Inform - receiving and giving information	
Customer satisfaction about the process of being a research participant Patient experience of research - understanding the purpose of the trial and consent Patient groups and communities – relevance to need Forensic analysis - of why trials failed to recruit to time and target	How might these help in any research you are doing?
Form – shaping and developing research	
Promoting involvement at early stage of design Assisting in process - info leaflets; communication about research; practicalities	What activities might people help shape research you are doing?
Influence – speaking up about research	
Issues - rare diseases; carers' needs, black or minority ethnicity, information leaflets, etc Ambassadors and champions - talking to groups, communities, Knowledge and understanding	What support might people need to help them speak about research you are doing?

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Template Advert for Patients and the Public to get Involved in Research

1 - Title / Headline

Patient and Public Research (detail what you will be calling people - lay advisor, panel member etc) wanted

2 - Key Questions to Include in the Body of the Text

Do you have experience of (condition) as a patient or as a carer? Could add any role here such as patient, family member

Have you had experience of (what experience are you looking for)

Do you want to influence (write what influence if any patients and the public would have in this area)

3 - Background to the Study

Describe some background to the study such as university, research group, funder, research team etc

When developing research it is important to understand patients' and carers'

needs to ensure that the research is in the best interests of the patient. For

this reason we want to invite people with experience of and / or affected by (condition) to act as advisors to our research.

4 - What Would this Mean for Patients Getting Involved?

You would be working in partnership with other patients, carers and researchers to write in what they would be involved in doing in your research or panel in (condition) services.

You do not need any previous experience, just a willingness to attend meetings and to give your perspective as someone with experience of (condition).

The position is voluntary but training and support will be provided, and all

travel and out-of-pocket expenses will be reimbursed. (detail here what expenses you will pay)

You should live in (detail any specific location, Trust or hospital) or have used the healthcare services in this area.

If you are interested in finding out more please contact name on number or via email give email or (consider adding an alternative contact) For further information - give details of your organisation or research group website

Adapted with kind permission from *Patient and Public Involvement in Health and Social Care Research: A Handbook for Researchers by Research Design Service London*

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Example Role Description

Role name e.g. User representative on Steering Group for X Research Project

Summary:

Purpose of steering group / main aims and objectives.

Background:

Project name e.g. Dermatology Research Steering Group: This section should

include (where relevant):

• A short history of the project or group, you may also want to include

details about the university and or department.

• An overview of why you are inviting patients and the public to join

the group.

• A brief explanation of the main topics that will be discussed and

decided upon at the meetings.

• What will the outputs be? For example, for a project it could be research

reports & lay summaries or for a steering group it could be decisions on what research is funded / approved.

• Who makes up this group? List names, their role and where appropriate

what organisations they represent.

• You may need to add start and finish dates for a project.

Matters for consideration by user representatives:

Conflicts of interest: As a representative you will be required to disclose any involvement you may have with other organisations, government bodies or corporate / commercial interests which could result in a conflict of interest with the work of you may need to give examples here. (this may not always be appropriate)

Confidentiality: As a representative of the [X Research Project at X University] you are asked not to share confidential information you may have received as a result of your position. This should be discussed with the project group and / or contact person.

Roles and responsibilities of user representative:

1. Duties

• To attend in person: include location, date, frequency of meetings

• To be available: include other means such as telephone / e-mail etc

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•To represent: the patient / lay user views of the X Research Project at

other meetings you are asked to attend

•To contribute to: discussion within the project steering group

• To contribute to: what activities will you involve people in?

2. Qualities

Users / lay persons / patients representatives should have experience and

knowledge of [condition]

• As a patient

• As a family member or carer of a patient

• As a member of an organisation that represent patients' / the public's

interests in issues relating to [condition]

Essential Criteria

• Understanding of the issues relating to having [condition]

• Be able to maintain confidentiality

• Have the time to attend meetings (either / preferably face-to-face or via telephone)

Add or delete criteria as appropriate - for every project or panel there will be different criteria and needs.

Desirable Criteria

• Have access to a computer and e-mail

• An understanding of the NHS

• An understanding of research processes and procedures

Remuneration:

User representation / lay panel members / patients on this project are paid / unpaid [you decide]. However, travel expenses and out-of-pocket expenses will be reimbursed in accordance with [Trust Policy / INVOLVE] (a summary should be given to the user representative.) Refreshments will be provided where appropriate.

(You may also wish to provide other expenses such as accommodation at your own discretion, ideally all out of pocket expenses will be covered, particularly travel expenses)

You should decide which costs you will cover, in-line with your department / trust policy and what the needs of your patients are.

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Support:
User representatives / patients / lay persons are able to access support and advice from the (Group Chair, key contact person - who is this in your project?) and other members via email, telephone or in person. (List contact names and numbers / email addresses.)

You should also state something here about providing access to resources that the user may need, for example literature (e.g. glossaries of terminology etc) and that you will support their involvement by asking them for regular feedback on their experience and responding to their needs.

Are there local relevant training courses you will send them on or suggest they attend? Are there other courses you have access to which they could attend? (such as Building Research Partnerships)

Further Information:

Provide them with research project website or university website. Other topic relevant websites or organisation details. A staff member's contact details.

Glossary:

Add definition of words or acronyms that have been used in the document and information on where to find out more.

Adapted with kind permission from *Patient and Public Involvement in Health and Social Care Research: A Handbook for Researchers by Research Design Service London*

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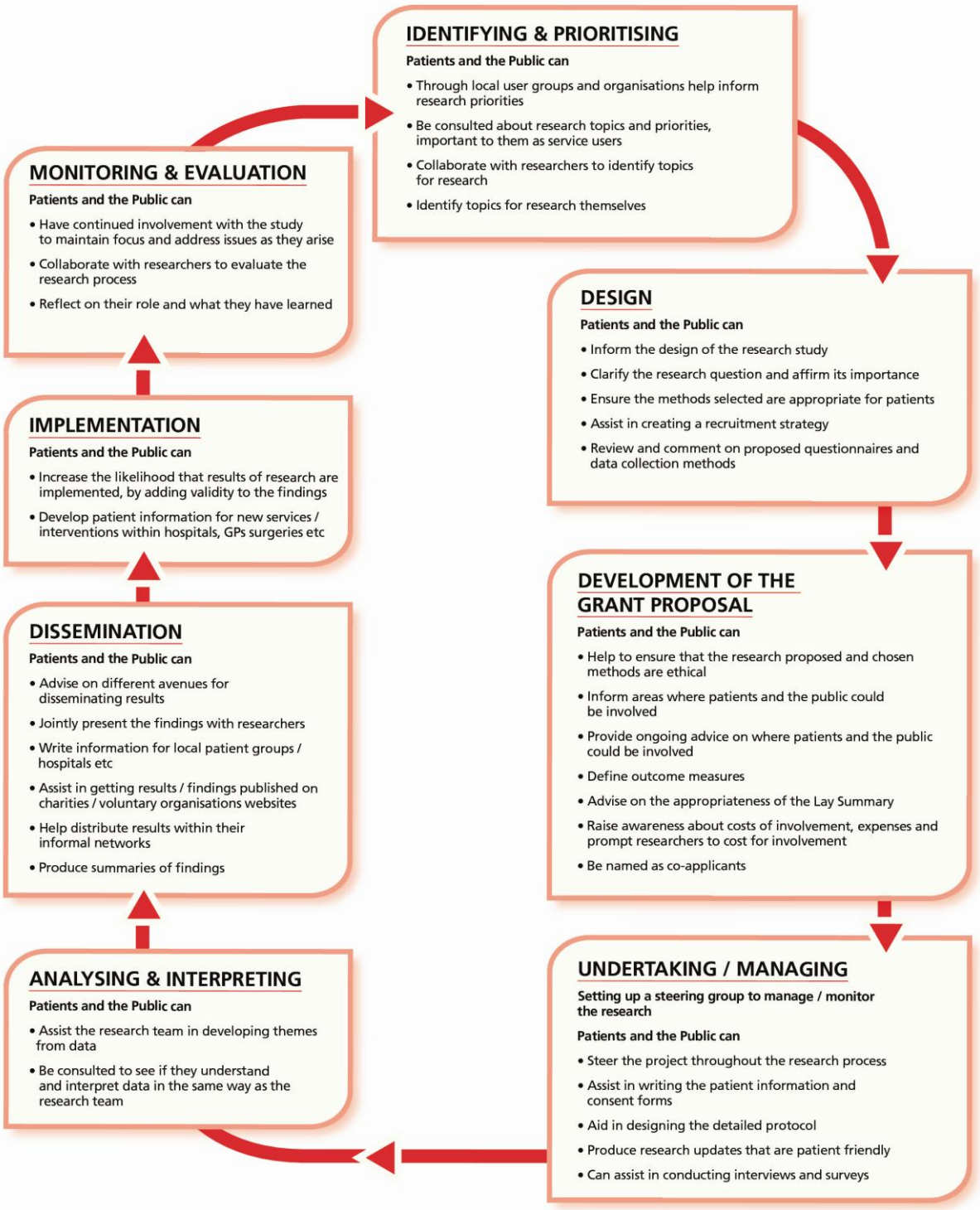
How to incorporate patient and public involvement in the research process



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Adapted with kind permission from Patient and Public Involvement in Health and Social Care Research: A Handbook for Researchers by Research Design Service London

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WE ARE MACMILLAN. CANCER SUPPORT

Using the Ways of getting involved diagram (see over page)

About the diagram

This is an attempt to visualise all the ways that you can get involved with improving cancer services.
Although it may look like a map, there is no right or wrong way to try things. It's just a way of grouping all the places you can get involved and showing how they work together.

How to use it

First of all, don't panic! It's quite simple. Everything on a green line is where Macmillan runs a service where you can get involved in improving it. Everything on a blue line is where the National Health Service runs a service you can get involved in improving. The red line represents the internet. While many services will have corresponding websites, the red line indicates where there are specific online tools or services to help you get involved and make a difference.

The interchanges are good starting points. They represent places you can go to that might be able to help you find your next best step. For example the Macmillan involvement co-ordinator interchange or the Macmillan Support Line interchange might send you to a specific Macmillan department, a government department or put you in touch with your local community centre – or anywhere else they think might be able to help you on your journey to improve cancer services.

Getting involved

There's no right or wrong answer about the best place to start getting involved. This diagram has been designed to show you all the ways you can get involved and to remind you that if one path doesn't work, there's always another way.

Taken from: http://www.nhsemployers.org/SiteCollectionDocuments/NHS%20in%202013%20explanation%20poster_A4.pdf June 2013

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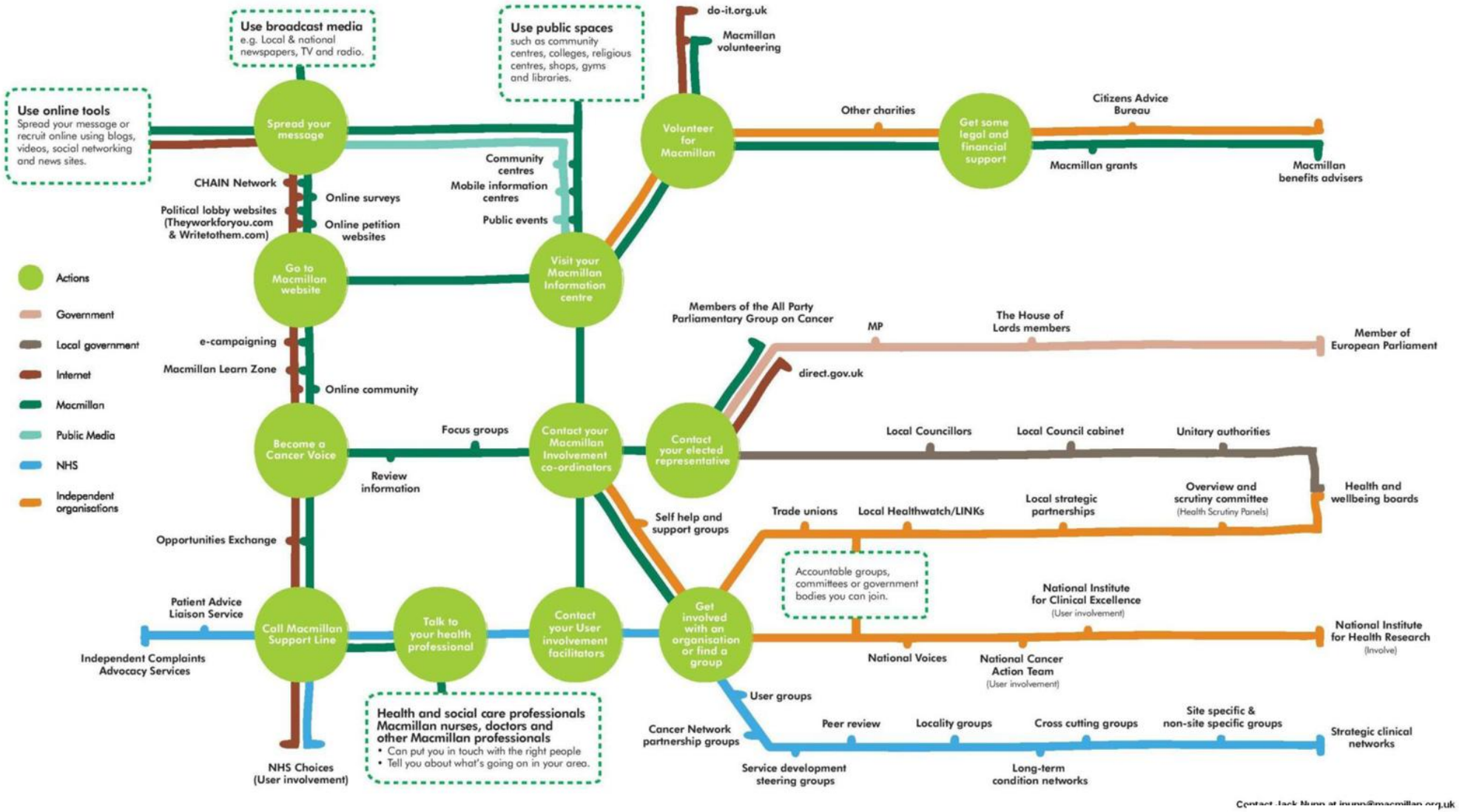
WAYS OF GETTING INVOLVED



Contact Jack Nunn at jnunn@macmillan.org.uk

Who I met (Name)	Contact details	What I want to talk to them about

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Who I met (Name)	Contact details	What I want to talk to them about

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ACTION PLAN

Handout

What I would like to achieve is...

The next action I should take to achieve this is...

The result of this action might be...

Some other actions I can take to achieve this are...

I can get support from...

Some challenges I might face could be...

I could overcome these barriers by...

By this date _____ I will have...

Fill out swap sheet, tear out and hand to your facilitator

Action plan swap sheet

Name _____

Contact me by phone or email or post:

_____

_____

By this date I will have...

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CLIMBING THE LADDER OF INVOLVEMENT

The Ladder of Participation is a model that can be used to examine where you are in terms of service user involvement now and where you want to be in the future:

FULL CONTROL: Service users control decision making at the highest level.

SHARING POWER: Service users share decisions and responsibility, influencing and determining outcomes.

PARTICIPATION: Service users can make suggestions and influence outcomes.

CONSULTATION: Service users are asked what they think but have limited influence.

INFORMATION: Services users are told what is happening but have no influence.

NO CONTROL: Service users are passive consumers.

Write what rung of the ladder you think you are on now:

Write some ideas about other ways you could influence services and decisions about services:

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KNOWLEDGE AND SKILLS GRID

Handout

Knowledge is information you have in your head; a skill is the ability to use knowledge to achieve something.

Skills	Knowledge
Skills I already have *(for example driving, speaking English)*	Knowledge I already have *(for example a knowledge of my community or local information resources)*
Skills I have that I would like to develop *(for example talking to people affected by cancer)*	Knowledge I would like to develop *(for example an understanding of cancer and its treatments)*
Skills I don't have but might need *(for example using the internet to communicate)*	Knowledge I might need *(for example a knowledge of funding opportunities)*

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Funding Applications

Funding applications submitted for **Health & Social Care Research & Development (HSC R&D)** Doctoral Fellowships have five criteria for involving patients and the public (PPI).

1. Does the proposal involve service users and the Public in a role other than research applicants?
2. Has the applicant chosen an appropriate user or public group to be involved?
3. Is the proposed level of Patient and Personal Involvement (PPI) appropriate?
4. Does the proposal demonstrate an understanding of the benefits of PPI?
5. Does the application aim to incorporate PPI in the reporting / disseminating of the outcomes of the study?

Ignatius Maguire, a public representative, a member of the Awards Panel offers some key points about completing the section in the research proposal about involving people as well as a personal perspective.

Some general points for Research Proposals from Ignatius:

- Personal contact i.e. talking to someone always looks like a positive start on the road to engagement.
- Seeking out an appropriate focus group and ' picking their brains' is a clear way forward but be prepared to offer something to the group in return.
- It may not be difficult to form a focus group if no existing group appears appropriate.
- If people are willing to assist be considerate about their time and the extent to which they can participate. Show consideration and gratitude in tangible ways e.g. offer expenses, child care facilities and time / locate meetings to suit willing participants.
- Advice is always readily available from the R&D office. It should probably be the first place to target for appropriate advice.
- Do not present extracts and lifts from the Involve website as an explanation of your attempts to address the PPI requirements!
- Have a plan which looks like a plan and not a collection of disjointed notions and names dropped here and there to (hopefully) tick the box.

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If a researcher, at the outset, has a focus on the benefit of the proposed research to the Public and consciously maintains that focus throughout the life of the project the involvement of the Public in the identification, preparation, participation and dissemination will be automatically achievable and apparent to all.

Ignatius Maguire offers a personal perspective on his consideration of the HSC R&D questions…

I can easily verify that not all researchers appear to understand the requirements of completing the section in their proposal about involving patients and the public in research. It is also clear that those who take the time to understand what they need to do will succeed and it will be obvious from their applications that they are compliant with the level of engagement required.

So what do I look for in PPI terms and expect to see in a funding application?

The first aspect is self-explanatory but I will always allow for the capacity or potential within each application i.e. to involve service users and the public. Clearly if the proposed research is laboratory based there is less capacity but there is always room to engage if there is a willingness to so do. If the research is about children the obvious people to target are parents and carers (and children if deemed appropriate and permissions obtained); if an elderly population then families and carers should be the target (as well as the willing elderly) and if focuses on a disease or condition then I think those who have survived or are coping with the condition (and their carers) are a predictable starting point for engagement.

In terms of choosing an appropriate group with whom to engage, there are innumerable groups of varying size and composition but the key word is appropriate. It should be clear that the chosen group has relevant experience and people capable of making a worthwhile contribution to the project.

The level to aim for is one that will engage the interest of the target audience and retain that interest through an appropriate level of involvement. People need to feel involved and to feel their views are being received appreciated. Not enough engagement will result in people losing interest and too much information will leave people overwhelmed and lead to rapid disengagement! Representation may also need to be appropriate in terms of a geographical area and clearly it would be beneficial if people are genuinely representative of a bigger group.

The benefits of PPI need to be firstly appreciated and accepted by the researcher and if that appreciation is in place at the outset the choice of service users and groups and their subsequent engagement should flow through the application and should be ‘ jumping off the page’ when I read it!

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38	2/3

Finally, the dissemination of information is vital. This is not a time for 'an arm round the homework' and there has never been such a selection of ways and methods of telling others about whatever we have been doing! It's merely a question of choosing the most appropriate vehicles for dissemination so it would not be best to rely on websites solely, if the target audience does not have access to technology or is not computer literate. I think that regardless of what stage (in the project) information is being disseminated the researcher needs to ensure that the message is received by the target audience in an appropriate way.

Applicants should be able to describe how service users and the public have been involved in the project to date **and** how they will be involved as the research progresses.

The past tense refers to the extent of involvement in identifying the research topic and/or prioritising the research question(s) and / or any involvement in the preparation of the application. The present or future tense refers to the ongoing involvement as partners/ advisers in the proposed research and the benefits of this should be highlighted. Researchers are asked to justify the level of involvement.

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38	3/3

Untangling the terms

Here are some commonly used words and terms. Try and match them with the definitions and see if you agree with them. Discuss which ones you think might be most appropriate for different scenarios. If you have any examples of these, please share them.

Word or term	**Definition**
Representative	Noun (a person): Adjective (a description):
Lay person	
Involved	
Engaged or engagement	
Public dialogue	Public dialogue does not claim to be fully representative, rather it is a group of the public, who, after adequate information, discussion, access to specialists and time to deliberate, form considered advice which gives a strong indication of how the public at large feels about certain issues.
Survey	
Focus group	
Reference group	
Advisory group	
Steering group	
Task Force	

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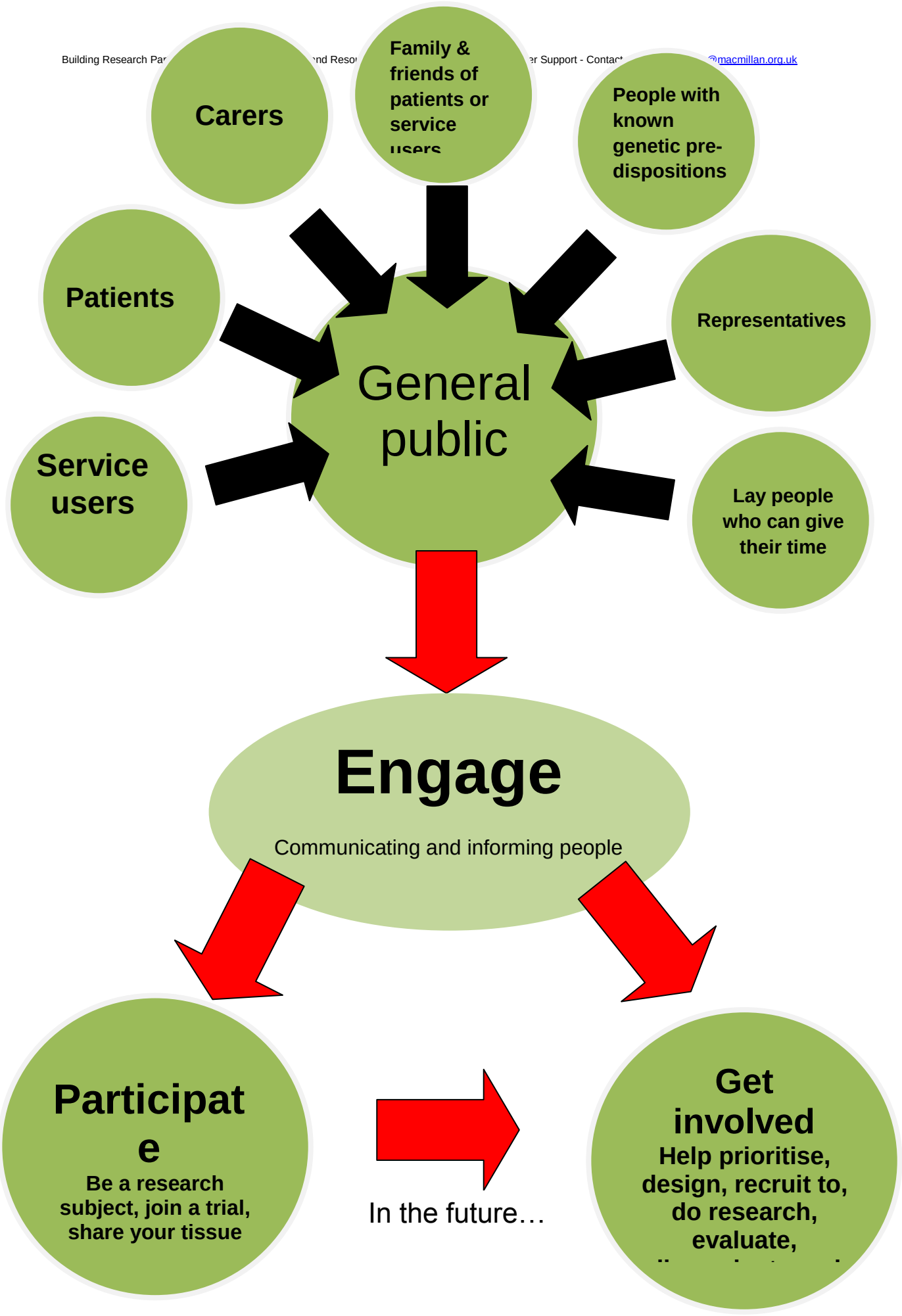

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BUILDING RESEARCH PARTNERSHIPS

Feedback Form

Why are we asking these questions?
The information collected will assist us in identifying how effective the learning event was in meeting participants' needs and help us to improve the learning events we offer. Any information you provide will be treated and held in accordance with the Data Protection Act 1998.

Name: **Organisation/location:**

Date: **Facilitator(s):**

Q1. Where did you hear about this event?

Q2. Please describe the area/s of the event that you found most valuable/most enjoyable:

Q3. Please describe the area/s of the event that you found least valuable/least enjoyable and/or areas that could have been developed further

Q4. How do you intend to apply what you learnt on the event? What will you do differently? What do you think will be the effect of this?

Q5. What recommendations would you like to make for future events?

This event uses free resources developed by Macmillan Cancer Support and is part of the 'Building Research Partnerships' project. The facilitators have been trained by Macmillan to facilitate this event and use these resources. You can learn more about this work here:

macmillan.org.uk/researchlearning

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41	1/2

Please tick the relevant box to show whether you agree or disagree with the following statements.

Statement	**Strongly agree**	**Agree**	**Don't know**	**Disagree**	**Strongly disagree**
Did you feel that the event was useful?					
Did you feel that any learning needs you identified when registering were met?					
The learning resources used helped me to learn					
The trainer facilitator(s) were sufficiently knowledgeable about the subject					
The facilitator(s) used a range of activities to appeal to different learning styles					
The event was structured and paced well					
The facilitator(s) made the subject interesting and enjoyable					
The group of learners was managed well by the facilitator(s)					
I found the opportunity to learn and share with other people useful					
I learned what I expected to learn on this event					
I would recommend this event to others					
I was satisfied with the information and administrative support I received prior to the event					
The venue and refreshments were satisfactory					

Overall, I would rate this event as…(circle)	Excellent	Good	Average	Poor	Very poor

If you have any other comments or suggestions then please write them here or attach them:

Macmillan Cancer Support would like to follow up with you within a few months' time in order to understand whether this event helped you in the longer term and if so, in what ways. This would mean completing another short survey by telephone or online. If you would be willing to be re-contacted for this, please provide your contact details below, indicating your preferred method of contact:

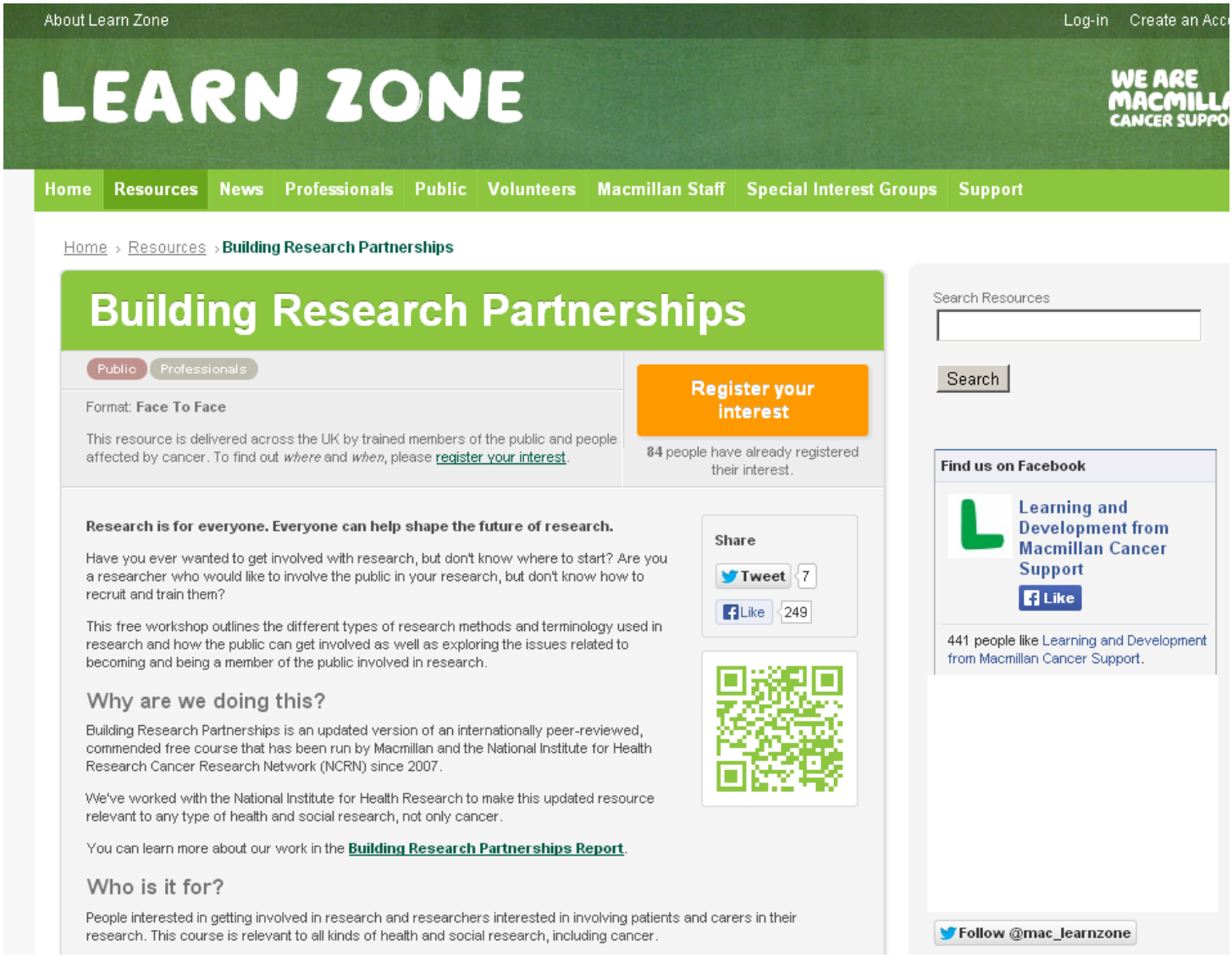
Email address/Telephone:

Also, can we keep your information to inform you about our work and ways you can support us? Your details will be kept securely and will only be shared with those who work on our behalf or with trusted partners who work with us to provide you with support. **Yes/No**

#	P
41	2/2

Building Research Parnerships Online

Visit macmillan.org.uk/researchlearning



Please note that everything from this point of the manual onwards is also included in the 'Operational Guidance'. This section has been included for convenience but the most up to date guidance can be found here:

http://goo.gl/EgHuDh

Checklist and timeline when facilitating a course

If you are involved in facilitating 'Building Research Partnerships' this sections gives a checklist with some helpful hints and tips about the things that will need doing and in which order. For a more detailed explanation of what support you will be offered by Centres and Macmillan, see the 'Operational Guidance'.

Initial request

If you are asked to facilitate a course, you should check the following:

Qualified - If you've been asked to facilitate a course ensure that you have a record of evidence that you have been trained to run the course. Some Centres will also require evidence of additional qualifications such as Equality & Diversity training.

When and where – Once you've been asked to facilitate a course you'll need to confirm your availability as soon as possible. Online tools such as doodle.com can make finding dates easier. For your records, ensure that the person organising the course has confirmed, in writing, the date and location and be sure to respond in writing. This is usually done via email. The centre will then contact their local Macmillan contacts who will ensure that the date appears on the Macmillan public calendar.

Main point of contact – It's important to establish who your main point of contact at the centre will be. This contact will be the person who is organising the course at the Centre who you will go to first for everything regarding this event, including all financial and administrative issues. The Centre will also be organising the venue and catering, so ensure you know all the information participants might need.

Travel and accommodation – Do not book or pay for any travel or accommodation without confirming with your main point of contact. Centres may have specific guidelines about what travel, accommodation and expenses may be claimed. This must be agreed in advance between the facilitator and the Centre. In some cases, Centres may book travel and accommodation for you but in all cases they should offer to pay these costs.

Needs of participants – Macmillan has created a registration form for participants to complete before attending courses. This collects information about whether people consider themselves to have a disability or any other condition which may affect their ability to participate in the learning activities. It also collects information about what people hope to learn and how they hope to apply it. Prior to running the course it is important that Centres share any relevant information with you in good time (in accordance with the Data Protection Act 1998). Where appropriate, you must use this information to suitably adapt the material delivered in your session to match the desired learning outcomes of the participants. If you have difficulty accessing this, please contact your centre or local Macmillan contact. If the facilitator thinks a meeting BEFORE the course is required, the centre must agree this and any additional costs.

Resources – Are there any local trials or research taking place that the organiser can send you any information about? Can they send you through some Patient Information Sheets or bring some along? If necessary, identifying information (such as names) can be removed.

A few days before

At least 7 working days before, you should check the following, allowing for time for things to be posted if you do not have them:

Materials and resources – you should agree with the Centre who is printing what and what will be needed where. Centres should cover all printing costs and facilitators should check with their main point of contact before printing anything themselves. This should be informed by the numbers and needs of participants and their desired learning outcomes. Venues will usually provide pens and flip chart paper. If you're planning on using a projector or any other technology or learning aids, ensure that you have informed your main point of contact. Ensure you have:

- **evaluation and monitoring forms**
- relevant handouts and resources
- post-its, pens and name label stickers if you use them

Room layout – this can be a good time to confirm the room will be set up in a way that will save you having to do this on your own on arrival.

Directions and contact details – Do you know where you're going. Who do you call if there's a problem? Do relevant people have your contact details?

Delegate list - For reasons of fire safety, you MUST have a register of all participants (as well as the facilitators). Make sure this is sent to you and printed off.

At the venue

On arrival at the venue you should check the following things. Please note that you should arrive at least 1 hour before the start of the session to allow time:

Safety and domestics – Find out where the fire exits are and if there are any planned fire drills or alarms. Locate the toilets and any disabled access toilets. Is there any food or tea and coffee? What time is this arriving? How is the temperature of the room controlled?

Welcome and signs - Is the room signed and easy to find? Does reception know the plans? Is anyone able to welcome and direct people?

The room

It is very important that you take charge of how the room is set out, remember, it is your session and you need to be as comfortable with it as much as the participants do.

The configuration of chairs can really affect the group dynamic. You may want to experiment until you find the seating that suits you best but remember that you will require delegates to write and work together and some may wish to take regular notes through the day so table or writing space may still be necessary. With all configurations it's important that everyone can see you, no delegates are hidden behind others and that each feels you can communicate with them both verbally and with eye contact. Sessions held on long boardroom style tables are the most difficult to work with and should be avoided when possible.

Ensure that anyone with sight or hearing problems is seated appropriately.

Effective configurations include:

- 'camp fire' arrangement - where everyone sits in an inward facing circle. This also avoids having tables in front of people.
- Half moon of chairs with the facilitator at the front.
- Banquet style – three small tables with groups sat around them. Be sure to mix people up regularly if you use this arrangement.

Ensure that the room is welcoming and tidy by making and food and drink accessible, drawing blinds to let light in, opening windows if it's stuffy.

Consider writing a welcome note, the name of the course and your name in a visible place.

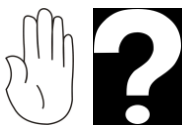
You could place the 'Who I met' sheets around the room or on tables at this point.

As participants arrive

- Welcome people as they arrive, introduce yourself (and if necessary your co-facilitator) and thank them for coming. Agendas normally allow 30 min for arrival and settling in.
- Ask people to sign in or tick them off as they arrive. **The list of delegates must stay with you all day for reasons of fire safety.**
- Leave the broad introduction until all are present or until the scheduled start time.

Ready to start?

- Welcome people and thank them for coming and give a brief introduction about the day.
- Get people to say their names, what they'd like to learn or gain from the training.
- If appropriate, ask them to include any experience of an illness they want to share or what motivated them to come to the day.
- Write what people want to learn (on a flip chart or something similar) and return to this at the end of the day to confirm people learned what they expected.
- If someone says something that will not be covered in the session, don't write it down and mention it won't be included
- Clarify course content, format and mutual expectations of the day and ask if anyone has any anxieties about the day.
- Draw pictures of the words in **bold** to prompt a discussion and consensus about the following:



- **Fire exit and alarms** – make sure people know about these
- **Toilets** – do people know where they are?
- **Clock** – agree times for lunch, breaks and finishing. Does anyone need to leave early (mention they'll need to fill in an evaluation form before they do).
- **A sealed envelope** for a discussion on confidentiality
- **Spelling tick** – all spelling is korrect
- **Thermometer** – people should say if the environment of the room is uncomfortable
- **TLAs** (with a line through it) – This stands for 'three letter acronyms'. Please try to avoid using any acronyms as they can alienate those who don't know them
- **Hand-up** – mention that people should feel free to say anything at any point, but some people find this hard and if they prefer they can raise their hands to signal they want to speak

- **Question mark** – Remind people there is no such thing as a stupid question. Ask if would people like to add anything else? More experienced facilitators may wish to open up the session by stating that the agenda is a guide only and if the group have specific areas they want to explore, which may not be on the agenda, then that will be accommodated during the day

During lunch

- Ensure that people know where food is and that everyone's preferences have been catered for.
- Talk to any participants who might need extra attention and encourage networking where necessary.

Close

- Collect evaluation forms – (send hard/electronic copies to Macmillan contact)
- Encourage participants to swap contact details (using the 'who I met' sheet)
- When leaving the venue, try to leave it as you found it.
- Ensure that relevant venue staff know you have left.
- Relax!

Training facilitators

Macmillan's facilitators training for this course has been designed to align with the National Open College Network (NOCN) standards, although no formal qualification is offered.

Observing other facilitators

An essential part of Macmillan's Quality Assurance framework is ensuring that our facilitators and trainers share best practice, learn from each other and maintain a consistent high quality throughout all our training courses.

We have developed a peer-observation framework which encourages the sharing and development of all the skills and experience of the facilitators trained to run this course.

The intended outcomes of peer-observation are:

- To ensure that innovation is encouraged and shared
- Feedback is given and received in order to encourage continuous improvement
- The development of facilitators and resources is supported

We do not offer training on observation skills, but below are some ideas and tips which may be helpful if you are observing or being observed. *Please note, senior facilitators should ensure that associate facilitators understand this section of the manual.*

How do I observe?

- **Do** sit as part of the group and take part in every aspect.
- **Do not** feel you need to sit 'out' or be separate in anyway, including sitting at the back of the room. This can negatively affect the group dynamic.
- **Do** feel you can be involved in group discussions.
- **Do not** lead activities or discussions or introduce new topics unless you have agreed this in advance with the facilitator you are observing or if the facilitator has specifically asked you to.
- **Do** feel free to tell the group why you are there and who you are. You may consider wording it as 'I'm here today as I also facilitate this course and I'd like to pick up some tips'. If you'd like a more formal statement, try 'I'm here as part of Macmillan's Quality Assurance framework which helps make sure all the facilitators are sharing the best ideas'. There's no need to say you are 'observing'. If you are unsure how to describe what you're doing, consider discussing this with the facilitator before hand.

What am I observing?

This course is evaluated using Macmillan's standard assessment criteria. In addition, each activity has clear aims, outcomes and key learning points. These can be helpful things to use as a reference when structuring feedback from an observation.

We've included some generic criteria here to give an idea of what things to look for when observing and giving feedback.

- Evidence of preparation
- Active listening & and positive responding plus use of open questioning
- Controlled and focussed discussion
- Managed time effectively
- Appropriate use of resources (such as handouts)
- Did it cover the key learning points and/or did it match the learning expectations of participants?
- Chairing skills (the ability to manage the group tactfully and inclusively, including aggressive participants)
- Delivery skills:
    - clear speech (right volume and pace)
    - simple language free from acronyms
    - eye contact

Other things to think about:

- Was it interactive?
- Was it presented in an interesting or engaging way?
- Were the learning objectives met?

Here are some more general things to look out for when observing a facilitator:

- Are they 'teaching' or telling rather than 'facilitating'? For example, are they encouraging learners to reach their own conclusions through a combination of information and open questions, or are they telling learners what they should think and why? If they are 'telling' too much, tell them!
- Are they encouraging group discussion and including all group members?
- Do they notice and assist 'quiet' or reticent participants in an appropriate way?
- Are they mixing up the group enough and encouraging networking – for example, creating different pairings and groupings throughout the day.
- Are they flexible? If the group of learners has specific learning outcomes, can they adapt and change the programme of the day as required?
- Are they assessing the retention of the learners through frequent and subtle informal questioning?
- Are they checking understanding? If they explain an activity, are they going around the room checking people understand it?

Remember - providing honest and helpful feedback to each other can be a really constructive way of developing skills. Please be tactful, but don't avoid constructive criticism. An observer should be seen as a 'critical friend'.

How do I share observations?

This will depend on each individual but often the best way to do this is to sit down and have a short private conversation immediately after the course. Sometimes the best place to start a discussion is by asking '**so how do you feel that went?**'. If you have any notes, you can use these to guide the conversation and share these with the associate facilitator after this conversation. You will be required to share the observation sheet with your centre, the facilitator and Macmillan. You may wish to fill this in as you go.

- When sharing observations, it is often advisable to 'sandwich' any ideas on how something could be improved between two things which were examples of best practice. This can avoid starting or ending with something which could be perceived to be a negative observation.
- Be specific. When possible, only share comments which will reinforce best practice or help the facilitator improve the learning experience of the participants.
- Have comments on each individual activity, rather than the course as a whole. You may wish to share these with the other facilitator in the form of notes for their reference. If you do have general observations, think carefully about how you will share these.
- Separate comments on the 'delivery style' of the facilitator from comments on the resources used. For example, 'I liked the way you spoke to the group and introduced this topic, but I think some of them found handout 4 too complicated', rather than 'I think people were confused at this point'.

Remember - If you have learned anything yourself and intend to use some tips you picked up from the facilitator, make sure to tell them, as they're likely to be very pleased to hear this!

Please note: If you have any serious concerns or doubts about the facilitator, whether it be ability or actions, attitude or behaviour, you may wish to contact you centre or their centre before passing this feedback onto the person you have observed. If there are serious concerns, the centre may wish to investigate further or possibly arrange further observation or development.

Finally

The most important thing is that everyone feels that observing and being observed is helpful. While the formal purpose of observation is to ensure quality and consistency, informally it's a chance to share ideas with other trainers and support each other in being

part of a wider community of trainers. All these notes are for guidance, so make it work for you!

Delivery style

The term 'delivery style' broadly means in what way information is given and received and what ways learning is encouraged.

Every teacher, tutor, trainer and facilitator will have their own delivery style and every learner will respond differently to different kinds of styles.

There isn't a Macmillan's 'style-guide' for running training, but Macmillan always favours any kind of learning environment which encourages shared learning, group discussion and experiential (active) learning.

The idea that **we all have something to give and something to learn** is central to any of our learning opportunities and all our trainers are encouraged to create a space in which people feel they can share openly.

'Active' learning, or learning through experience means that a person is doing something, or actively involved in shaping the learning process (e.g. contributing to a discussion). Passive learning requires no direct action or input from participants.

While much has been written about learning styles, it's more helpful to think in terms of 'retention', what people remember. The advantage of active learning is that it is easier to constantly evaluate the learning and retention through the use of open questions. Passive learning is more reliant on formal assessment to determine retention.

A famous model for explaining different delivery styles is Edgar Dale's 'Cone of Experience', which has been used for over half a century. While there is much discussion about the exact hierarchy, it is generally agreed that any learning through 'direct experience' is most often retained. Below this would be group discussion and at the bottom presentations and written information. It is interesting to note that '**active'** learning is not only more enjoyable than '**passive'** learning; it seems to be a more successful way of communicating information.

It's important to note that different styles are appropriate depending on different contexts and audiences and that sometimes a more passive style of delivery is unavoidable.

Becoming a senior facilitator

Some associate facilitators may wish to develop their skills and be trained to train other facilitators.

This decision would need to be supported by the centre which has sponsored your development and Macmillan should also be informed. It is recommended that an associate facilitator should have run between 3-5 courses before training other facilitators. They should also secure a reference from an existing senior facilitator they have worked with.

How to train associate facilitators

Each associate facilitator will have their own style and ideas, as will each senior facilitator. Rather than set out clear instructions as to how a senior facilitator should train new associate facilitators, below are some guidance notes for senior facilitators training new associate facilitators at each stage of their development.

Throughout the process of training facilitators, the “Facilitators’ Manual” is always the best place point of reference. This has clear learning aims, outcomes and learning points which should be constantly referred to.

The most important role of the facilitator trainers is to support the new facilitators developing their own ways of achieving the learning outcomes, rather than telling them how to run activities or give them a ‘script’. While initially, in practice, the new facilitator may chose to closely mimic the trainer, any innovation by the new facilitator should be encouraged and evaluated. This may include the development of new resources or activities.

Finally, it’s worth mentioning that this is by no means a one-way process. Encourage new facilitators to ask questions and challenge you on why you do things in certain ways. Always be ready to explain and adapt yourself!

Pre-training

Anyone who is interested in being a facilitator should have attended and participated in a course before they can begin being trained as a facilitator.

Once they have expressed an interest, they should be given the "Facilitators' Manual" to read through. It is advisable that they are given the manual associate facilitator after attending as a participant so that they can initially see it through the eyes of a participant, rather than a trainer.

Aim: To provide an opportunity for people interested in becoming facilitators an idea of how the course is run.

Outcome: Potential facilitators will be able to explain the role of 'facilitator' and the aims and outcomes of the course 'Building Research Partnerships'.

We recommend that people interested in being facilitators are paid at Involve's rate of 150 a day for this 'pre-training' session.

First session - shadowing

Aim: To provide an opportunity for the associate facilitator to gain experience in how the facilitators' manual and other resources are used to achieve specific learning outcomes.

Outcomes:

- Associate facilitators will be able to demonstrate an understanding of why certain activities achieve certain learning outcomes
- Associate facilitators will be able to demonstrate their facilitation skills by leading on some pre-agreed activities
- Associate facilitators will be able to explain how they might use and adapt resources when leading activities at the next session.

Before the first shadow-session – the senior facilitator training the associate facilitator may wish to speak or meet to agree which activities the associate facilitator feels confident in leading or joining in with. This will vary but it is suggested that the senior facilitator leads a majority of the activities to provide an opportunity for the associate facilitator to reflect on why the senior facilitator chose to run certain activities in certain ways.

A good first session for an associate facilitator to run is 'What is research'.

After the course, the senior facilitator and the associate facilitator should discuss the session, highlighting areas that went well, and exploring what could be improved. The senior facilitator should encourage the associate facilitator to suggest ways that it could be improved.

We recommend that a total of one hour should be needed for a pre-brief and a de-brief. This would equal a maximum of one hour of developmental work at 25/hour for the senior facilitator. Anything over this must be agreed in advance with Macmillan in accordance with the casual worker policy.

We recommend that people shadowing their first session should be paid at Involve's rate of 150 a day.

Second session – leading with support

Aim: To provide an opportunity for new facilitators to gain experience in using the facilitators' manual and other resources to achieve specific learning outcomes.

Outcomes:

- Associate facilitators will be able to demonstrate an ability to run certain activities achieve specific learning outcomes.
- Associate facilitators will have demonstrated an ability to adapt an activity or resource to achieve a specific learning outcome
- Associate facilitators will have demonstrated an ability to be flexible in the delivery and planning of learning activities.

As much as possible, encourage the associate facilitator to lead the day. They should certainly introduce the day and do the welcome, introduction and 'the 4 Gs'. They should be running a majority of the activities which should be agreed beforehand. With some they might not still feel confident leading on, and the senior facilitator should lead these.

If at the end of this session the senior facilitator and/or associate facilitator feel that they need another chance to lead with support then this should be arranged before the associate facilitator proceeds to being assessed.

The senior facilitator should be prepared to give detailed feedback on each session that the associate facilitator ran, as well as some more general feedback.

Macmillan recommends that a total of one hour should be needed for a pre-brief and a de-brief. This would equal a maximum of one hour of developmental work at 25/hour for the senior facilitator. Anything over this must be agreed in advance with Macmillan in accordance with the casual worker policy.

We recommend that people leading the on their second session should be paid at the rate of 300 a day.

Third session – assessment

Aim: To provide an opportunity for associate facilitators to gain experience in using the facilitators' manual and other resources to independently run an entire course to achieve specific learning outcomes.

Outcomes:

- Associate facilitators will be able to demonstrate an ability to run certain activities achieve specific learning outcomes, independent of support from a senior facilitator.
- Associate facilitators will have demonstrated an ability to adapt an activity or resource to achieve a specific learning outcome, independent of support from a senior facilitator.
- Associate facilitators will have demonstrated an ability to be flexible in the delivery and planning of learning activities, independent of support from a senior facilitator.
- Associate facilitators will feel confident and able to run a course independently

The senior facilitator should not **need** to step in or lead at any point but should feel more than welcome to add or contribute to discussions. In every other way, they should include themselves as part of the group and participate.

We recommend that people leading for their final assessment should be paid at the rate of 300 a day.

Facilitator Assessment

The most important aspect of 'Building Research Partnerships' is the Quality Assurance framework. As Macmillan does not directly employ facilitators, it is important that we can work with partner organisations to develop trust in our facilitator training, so that we can 'vouch' for individuals who have been trained by Macmillan.

It is important that the assessment process is one which encourages learning and improvement and should be seen as 'double checking' that a facilitator is ready, rather than a test or examination. In order to create a record of facilitator training, there are certain formal aspects to it and documents, but the spirit of the process should remain one of learning and sharing.

In practical terms, the facilitator assessing may wish to join in and take part in activities. How and when they will participate should be agreed in advance, as the facilitator being assessed should have an opportunity to demonstrate they are capable of facilitating independently.

Once the facilitator has been signed off, they will receive a certificate and be added to the central database of facilitators.

Please note: The term 'internal verifier' is used in this context to mean a member of Macmillan staff who is signing off and 'vouching' for facilitators, after seeing sufficient evidence.

In order to gain a certificate allowing them to facilitate 'Building Research Partnerships', associate facilitators must be formally assessed. This section outlines the process and the documentation that is required.

The formal methods of assessment are:

Type of assessment	How it is carried out	Who assesses this
An assessment of the facilitator while facilitating a course or in a simulated environment.	A senior facilitator will observe the associate facilitator carry out the course or part of the course and ensure the **Associate Facilitator certification statement** is signed.	Senior facilitators, checked by internal verifier.

If the above method of assessment is not possible, a combination of the methods below is acceptable, though not preferable:

Type of assessment	How it is carried out	Who assesses this
Case studies	The associate facilitator must give two case studies which evidence at least two of the assessment criteria.	Senior facilitators, checked by internal verifier.
Reference	A written reference from somebody at the centre where the course was delivered.	Internal verifier.
Feedback forms and a self-assessment form	Sent to internal verifier.	Internal verifier.

Facilitator Assessment guide

This guide has been written to help senior facilitators assess whether an associate facilitator is ready to be 'signed off' and recommended as a facilitator who can lead independently of other facilitators.

Each individual assessor will give feedback in their own way but documents and templates have been provided to help structure the assessment to ensure that all aspects of the facilitation were lead well.

The most important thing is that the entire process is useful to the person being assessed as well as helping ensure the individual ready to facilitate independently.

Assessment documents

On the next few pages are the documents relevant to assessing an associate facilitator. Please note that the only documents which are **required** in order to certify a facilitator is the 'Associate Facilitator certification statement' and the Assessment Criteria document (in red), the rest are optional or for reference.

- **Associate Facilitator certification statement -** to be signed by senior facilitator and associate facilitator (and copied to Centre and research.learning@macmillan.org.uk)
- **Assessment Criteria** - to be completed by a Senior facilitator and reviewed by the internal verifier
- **Detailed Macmillan Assessment Criteria –** Optional – things to look for
- **Assessor prompt sheet** - Things to look out for
- **Appeals complaints and disputes**

Associate Facilitator certification statement

The named associate facilitator's signature below indicates that the associate facilitator:

- Has met all the assessment criteria, to the best of their knowledge
- Has completed a self-assessment
- Agrees that any work submitted is their own
- Believes they are capable of facilitating 'Building Research Partnerships' independently
- Has read and understands the Facilitators' manual
- Understands where they can go for additional support or training

Name of associate facilitator:

The named senior facilitator's signature below indicates that the senior facilitator:

- Has seen sufficient evidence that the associate facilitator has fulfilled the assessment criteria.
- Believes the associate facilitator is capable of facilitating 'Building Research Partnerships' independently

Name of senior facilitator:

Name of Centre sponsoring the associate facilitator:
Named contact and contact details:

A copy of this document must be sent to the Centre sponsoring the associate facilitator and to Jack Nunn at research.learning@macmillan.org.uk, after which it will be stored in a central database accessible to all Centres, in accordance with the Data Protection act 1998.

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Assessment criteria

Associate facilitators should be judged against these objective criteria in order to confirm that they meet the standards required to facilitate 'Building Research Partnerships'. They will be judged as 'met' or 'not met'. If marked 'met' this must be independent of support from another facilitator. If any assessment criteria have not been met, the internal verifier will lead a review and make recommendations. This may involve recommending further training and assessment.

Assessment criteria	Met (Yes/No)	Comments (optional)
Associate facilitators is able to demonstrate an ability to run certain activities to achieve specific learning outcomes.		
Associate facilitator has demonstrated good planning, including an ability to adapt an activity or resource to achieve a specific learning outcome.		
Associate facilitator has demonstrated good communication, an ability to be flexible in the delivery and planning of learning activities.		
Associate facilitator is able to facilitate an event independently, including overseeing and carrying out appropriate operational requirements, observed relevant any health and safety or equality laws or other relevant responsibilities.		
Associate facilitator demonstrated an understanding of the diverse range of learning needs and met these in an inclusive way.		
Associate facilitator has supplied evidence that they have met the assessment criteria.		

Comments:

Senior facilitator

Print name: Sign: Date:

Assessor

Print name: Sign: Date:

Detailed Macmillan Assessment Criteria

This document does not need to be completed, but has been included as it may contain helpful things to think about when observing and assessing anyone.

Session Details
Facilitator Name: Assessor Name:
Course: Venue:
Time of session: Date:
Number of people registered: Number of people in attendance:

Evaluation Outstanding / Good / Satisfactory / Requires Development

Observer Comments:

Key Strengths:
Areas for Development:

Facilitator Comments:

Signed: (Facilitator) Date:
Signed: (Assessor) Date:

Planning
What evidence is there of:

- effective initial assessment of individual needs, interests, aspirations and prior learning which informs learning plans
- clear planning and structure, with effective links to past and planned learning
- clear learning targets and goals (group and/or individual) which have been negotiated / agreed with participants
- a variety of planned learning and assessment activities and styles of teaching which support achievement of objectives and meet individual needs

Teaching and Learning
To what extent does the trainer:

- communicate effectively and motivate participants
- stimulate and challenge participants to achieve excellence or think differently

- establish good working relationships that foster learning
- show good subject knowledge and familiarity with recent developments in their field
- use a range of teaching and training methods and resources which secure the active engagement of participants
- promote equality of opportunity and actively address issues of gender, race and disability equality
- adapt learning activities, resources and assessments to allow participants to benefit fully from the learning experience
- manage participant feedback and respond to issues raised

Assessment and Achievement

What evidence is there of:

- Participants understanding what they are doing , how well they are progressing and what they need to do to improve
- achievement of good standards in participants' knowledge, understanding and skills
- achievement of agreed learning goals

Resources

To what extent do/does:

- accommodation provide a setting for good teaching, learning and support for all learners and offers a safe and healthy environment
- all participants have access to appropriate learning resources that match the demands of their learning
- good quality resources, including ILT, contribute to promoting learning and allowing all participants to participate

Guidance and Support

What evidence is there of:

- appropriate diagnosis of individual learning needs
- appropriate provision of additional support to meet individual needs
- appropriate support and guidance for participants, taking account of their social, educational, ethnic or linguistic background
- promotion of gender equality and challenge of stereotypes in participants' choices and expectations.
- promotion of race relations across all activities
- partnership working with interested parties
- provision of information on all the opportunities available and impartial guidance that helps participants choose the course which is right for them
- induction programmes which help participants settle in quickly, understand their rights and responsibilities and the demands of the course or programme

Best practice

- Was there anything you would do differently after observing?
- What worked well? Why?

Assessor prompt sheet

This is a one page more informal prompt sheet designed to help trigger ideas for assessment.

Preparation – pre-session
- knowledge of manual/handouts
- with co-facilitator

Initial greeting/mood-setting - welcoming…..warm….
- aids comfort/safety/enjoyment
- agenda …clear….engaging

Manner of delivery - eye contact/body language
- voice…clear….good level
- clear paraphrasing
- Did they check everyone in the group understood activities?

Listening - allowing participants' to speak uninterrupted/showing interest

Responses/comments show - interest and empathy
- contributions important and valued
- lead to good rapport and group dynamic
- praise for ideas
- no arguing/telling to do…
- reflecting back……open questions
- build on personal strengths
- tease out ideas for change

Finding solutions – take any opportunity to do…
- use group for ideas for solutions…… leaving own comments or ideas to last

Discussion - flexible in allowing it to continue when important/fruitful
- remains focussed
- reined in if necessary

Awareness of needs of individuals

Time management - start/finish on time

Appeals complaints and disputes

Senior facilitators who have observed and assessed associate facilitators will judge the individual against objective assessment criteria.

This judgement is reviewed by an internal verifier. In addition, senior facilitators will attend standardisation meetings to discuss assessment decisions to ensure that they remain objective and fair.

If the associate facilitator disagrees with the decision of a senior facilitator, disputes an issue or has a complaint that they would not like to discuss with the senior facilitator then they should contact the internal verifier. At the time of writing the internal verifier can be contacted at research.learning@macmillan.org.uk.

The appeal, complaint or dispute will be reviewed by the internal verifier and they will make a recommendation which will be copied to both the senior facilitator, associate facilitator and the Centre sponsoring the associate facilitator. The incident may also be anonymised and discussed at future standardisation meetings.

Sharing and Creative Commons

Using the materials and contacting us

Macmillan Cancer Support have shared these under a Creative Commons License in order to help people affected by cancer and the public shape the future of research across the world.

Please feel free to use and share the materials as described in the license.

We hope that this version will be the first of many updated versions, so please **contact Macmillan** at research.learning@macmillan.org.uk for information about updated versions and giving feedback.

Please note if you are using these at an event, please only say that you work for Macmillan if Macmillan Cancer Support are directly employing you to run an event. Otherwise, please state one of the following:

If you are running an event for another organisation (i.e they are paying you or you are volunteering) **and** you have completed training from Macmillan and are working within the Quality Assurance Framework:

> "I am facilitating this event today for *named organisation*, and have been trained by Macmillan to facilitate this event and use these resources. I work with other facilitators across the UK and we always welcome feedback about ways to improve events and resources"

If you are working freelance or are using these resources in any other capacity in any part of the world (i.e not part of the Macmillan Quality Assurance Framework) please state the following when appropriate:

> "The resources and/or activities I will be using today were developed by Macmillan Cancer Support and are part of the 'Building Research Partnerships' project. They form part of Macmillan's learning and development offer. This is an internationally peer-reviewed, commended free course that has been run by Macmillan and the National Institute for Health Research Cancer Research Network (NCRN) since 2007. Macmillan Cancer Support have shared these under a Creative Commons License in order to help people affected by cancer and the public shape the future of research across the world. You can read a report about this work here."

Please note, if you are using these resources in a freelance capacity, we always welcome feedback, ideas and suggestions for ways to improve them. If you are interested in finding out how to become a facilitator for this course, or would like to become part of the online community, please contact research.learning@macmillan.org.uk.

Acknowledgements

The development of this manual and resources has taken many years and is the result of the work of a number of people.

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- Jim Elliot

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- The Public Health Agency (Northern Ireland)
- The National Institute for Social Care and Health Research Clinical Research Centre (Wales)

Thank you to everyone who has supported Building Research Partnerships.

We would like to dedicate this resource in memory of Neil Formstone. In the spirit of his work, we hope that this resource will be useful for people across the world in helping them get involved in shaping the future of research.